

# PSYCHIATRIC CLINICAL DEVELOPMENT

For two decades, Medpace has worked with Sponsors to develop therapies in neuroscience. Our expertise in mental health studies and consistent track record of success as a full-service CRO ensures the flexibility to adapt to the unique needs of each trial.

## Indication Expertise:

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

As a therapeutically-focused CRO, Medpace's expertise and multi-disciplinary teams are experienced in many different areas. Our therapeutically-trained teams including clinical trial managers and program coordinators provide knowledgeable training to sites and help to mitigate challenges. Further, our experience with global regulatory authorities, coupled with early planning and collaboration with Sponsors, accelerates the path to approval.

***As a full-service CRO with a consistent track record of success, Medpace provides beginning-to-end expertise in mental health with the flexibility to adapt to the unique needs of each trial.***



## EXPERTS

- Led by in-house medical doctors with experience in psychiatry and neurology clinical development
- Integrated neuroimaging expertise
- Skilled medical, regulatory, and operations project teams

## EXPERIENCE

- Broad experience in neuroscience and mental health indications
- Phase I-IV global trial experience
- Drug, diagnostics, and device experience
- Strong relationships with key industry investigative sites
- Coordination of rater training and certification including subjective assessments, rater reliability, and scale validation

## EXECUTION

- Long-term relationships with investigative sites with proven track records in the execution of clinical trials for neuroscience and psychiatric indications
- Global imaging services through Medpace Imaging Core Lab
- Fully-integrated, web-based decision support system provides IWRS/IVRS, study product management, data management, laboratory management, and image management needs



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## MEDICAL EXPERTS

Our experienced medical doctors provide strategic direction for each study design, train operational staff, work with Investigators, provide medical monitoring, and meet with regulatory agencies. Medpace physicians and professional staff have in-depth knowledge of screening tools and rater scales to provide oversight for rater services including subjective assessments, inter-rater reliability, and scale validation. Our medical experts are embedded throughout every study from start to finish.

## INTEGRATED PROJECT TEAMS

The complexities of mental health research require a high-level of integration and efficiency. With our full-service model, Medpace offers strategic medical, regulatory, and operational experts and project teams. All team members are involved from project initiation to completion, providing seamless clinical development for Sponsors.

## MEDPACE CENTRAL LAB

Medpace Central Labs offer global lab services including an extensive menu of biomarkers that use state-of-the-art techniques for 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:

- Extensive biomarker testing menu
- Collaborative project management
- Timely kit/logistics team
- Global biorepository services
- Data management team
- ClinTrak® Lab, Laboratory Information Management System (LIMS)

## IMAGING CORE LABS

Medpace imaging core lab has over a decade of experience in global neuroscience trial management. Supported by a team of scientists, clinicians, technologists, project managers and coordinators, our imaging core lab can successfully integrate standard and novel neuroimaging biomarkers into Phase I-III studies from concept through design and execution.

### Capabilities:

- Standard diagnostic imaging
- Magnetic resonance imaging (MRI)
- Computed tomography (CT)
- Bone densitometry or dual-energy x-ray absorptiometry (DXA)

## 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.**

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MAKING THE COMPLEX  
**SEAMLESS**

