

PSYCHIATRY CRO

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:

- Substance Use Disorders
- Anxiety Disorders
- Attention-Deficit/Hyperactivity Disorder
- Autism Spectrum 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
- Advanced Nurse Practitioners provide an additional layer of expertise including patient and site perspectives
- 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 and networks
- Coordination of rater training and certification including subjective assessments, rater reliability, and scale validation
- Placebo mitigation strategies to limit the potential for placebo response through site and participant education
- Detailed knowledge of regulatory requirements for managing studies utilizing controlled substances, including DEA Schedule I investigational products

EXECUTION

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



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.

PLACEBO RESPONSE

Medpace has extensive experience in training site staff on effective strategies to interact with study patients and developing processes to educate patients about the requirements of a study, the use and need for placebos in clinical trials, the importance of honest and objective feedback, and active participation in the study.

MEDICATION ADHERENCE

Medpace's TrialPACE® ePRO/eDiary system can be leveraged to improve medication adherence with dosing reminders for patients, and notifications to site staff regarding missing eDiary entries allowing near real time follow-up with patients regarding missed doses.

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.

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.

ECG CORE LAB & CARDIAC SAFETY

Through Medpace's wholly-owned cardiovascular core lab, we provide ECG acquisition and analysis services utilizing industry standard devices and systems. As a fully-integrated service, this allows ECG results to be interpreted in the context of all the other data.

BIOANALYTICAL LAB

Leveraging state-of-the-art facilities, techniques, and instrumentation, our team of experts has experience in a broad range of small and large molecule bioanalytical and biomarker support.

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

MAKING THE COMPLEX
SEAMLESS

