MEDPACE

# EARLY PHASE PSYCHIATRY CLINICAL DEVELOPMENT

Early-phase study design is critical and deeply impacts predicting late-phase research outcomes. Ensure efficiencies with your early-phase trial by partnering with the fully integrated Medpace CRO with extensive early-phase expertise in neuroscience, including psychiatry. From consultation on protocol designs to our innovations in translational medicine, our therapeutically aligned team works as dedicated partners to adapt to the unique needs of each trial.

As a therapeutically focused CRO, Medpace's expertise and multi-disciplinary teams are experienced in many different areas.

Early Phase Psychiatry Expertise:

- Healthy Volunteers
- Psychiatry Patient Populations
  - Major Depressive Disorder
  - Substance Use Disorders
  - Anxiety Disorders
  - Attention-Deficit/Hyperactivity Disorder
  - Bipolar Disorder
  - Schizophrenia
  - Sleep Disorders
- Special Populations
  - Renal Impairment
  - Hepatic Impairment
  - Japanese, Chinese, & Korean populations for Ethnobridging studies
  - Pediatrics

***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

- Embedded physician leadership with experience in early phase psychiatry and neurology clinical development
- Therapeutically aligned medical, regulatory, and operations teams work as partners with Phase I Units to deliver projects according to each Sponsor's specifications
- Medpace Phase I Unit dedicated staff for the recruitment and screening of health volunteers

## EXPERIENCE

- Extensive Early Phase global trial experience in neuroscience and mental health indications
- Coordination of rater training and certification including subjective assessments, rater reliability, and scale validation
- 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

- State-of-the-art Phase I Unit Facility for management of studies in Health Volunteers
- Close working relationships with Phase I units with access to Psychiatry Patients as well as special populations
- Fully-integrated, web-based decision support system provides IWRS/IVRS, ePRO, study product management, data management, laboratory management, and image management needs

## STRONG RELATIONSHIPS WITH SITE NETWORKS

Medpace has close working relationships with site networks with inpatient capabilities, that are committed to meeting Medpace's high standards for study start-up, patient-centric conduct, data capture, and quality.

This allows us to complete early phase studies in patients with psychiatric conditions, renal and hepatic impaired populations, and ethnobridging studies in Japanese, Chinese, and Korean populations.

## PLACEBO RESPONSE

Medpace has extensive experience in training site staff on effective strategies to interact with study participants and developing processes to educate participants 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.

## MEDPACE 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.

## 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.

## LEVERAGE FULL-SERVICE SOLUTIONS FOR EARLY-PHASE STUDIES

The Phase I Unit draws on the extensive expertise of Medpace CRO to provide a full range of early-phase clinical research services, including regulatory consulting for early-phase development protocol design and writing, development of innovative processes for complex studies, pharmacokinetic and translational medicine consulting, project management, data management, and biostatistics.

Early-Phase Services & Study Designs:

- First-in-human (FIH)
- SAD / MAD
- Dose escalation
- Single or multiple dose studies
- Bioavailability / bioequivalence
- Drug-drug interaction
- PK/PD
- Food effect
- Phase IIa, Proof of concept
- Thorough QR / QTc
- Device and diagnostics
- Adaptive design

## MEDPACE PHASE I UNIT

The Medpace Phase I Unit is a 60-bed clinical research facility that provides high-end amenities to volunteers. With the ability to conduct clinical pharmacology studies in three independent patient units, the state-of-the-art facility was built to accommodate small and large-scale studies. Features include a 60,000 square-foot in-patient and out-patient facility, centralized laboratory processing, licensed Investigational Drug Services/Pharmacy, centralized food service, 24/7 security, and certified advanced cardiac life support (ACLS) personnel on staff.

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



MAKING THE COMPLEX SEAMLESS®