

# **Psychiatry Experience**

Mental health disorders are the leading cause of years lived with disability (YLDs), accounting for one in every six (15.6%) years lived with disability globally. As the leading cause of YLDs, psychiatric disorders are highly prevalent, often devastating diseases that negatively impact the lives of millions of people across the globe. Their etiological and diagnostic heterogeneity has been a long-standing obstruction to drug discovery. Further, clinical psychiatry trials are associated with unique methodological challenges and regulatory requirements. Operationally, sponsors execute these trials within a crowded space. These challenges collectively demand a CRO with psychiatry know-how from the ground up and the top down.

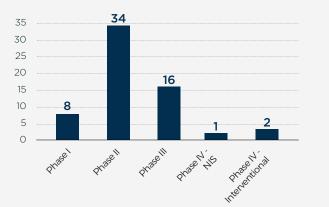
At Worldwide Clinical Trials, our experts understand the nuances associated with various psychiatric conditions, with thorough experience across a spectrum of mental health disorders.

## **Experience & Capabilities**

#### Full-Service Psychiatry Experience in the Last 5 Years

| Indication                     | Projects | Sites | <b>Enrolled Patients</b> |
|--------------------------------|----------|-------|--------------------------|
| Major depressive disorder      | 21       | 926   | 5,340                    |
| Schizophrenia                  | 11       | 253   | 2,231                    |
| Autism                         | 6        | 192   | 1,139                    |
| Generalized anxiety disorder   | 6        | 218   | 1,911                    |
| Treatment-resistant depression | 5        | 101   | 563                      |
| Substance use disorders        | 3        | 10    | 185                      |
| Post-traumatic stress disorder | 3        | 40    | 143                      |
| Bipolar disorder               | 2        | 27    | 357                      |
| Adjustment disorder            | 1        | 20    | 66                       |
| Anorexia nervosa               | 1        | 5     | 60                       |
| Postpartum depression          | 1        | 20    | 40                       |
| Grand Total                    | 61       | 1,818 | 12,395                   |

#### **Experience Across Phase I-IV**



## **Drug Classes**

- Central nervous system (CNS) stimulants
- -> Psychedelics
- -> Serotonin and norepinephrine reuptake inhibitors
- Selective p38 MAP Kinase inhibitors
- Atypical antipsychotics
- 🦻 Neurotoxin protein
- Nappa-opiod receptor antagonists

## The Worldwide Difference

Our team has contributed to clinical trial methods across psychiatric indications, publishing on an ongoing basis and analyzing psychiatric studies in all development phases with proof-of-concept and pivotal trial intentions. As a leading global CRO, we set ourselves apart from the rest with our long-standing contribution to methodological rigor and optimized protocol design in neuropsychiatry trials, where we offer you:



### **Therapeutic alignment**

Our operational and medical teams focus exclusively on CNS studies and have the relevant relationships and insights for the given indication.



#### **Executive leadership**

The company's founders and executive neuropsychiatry leaders head our Clinical **Research Methodologies and Scientific** Solutions teams.



#### Strategic engagements

We provide insight and guidance into the positioning of the compound and any agency interactions.



## **Clinical Outcomes Assessments**

We have a fully in-house Clinical Assessment Training and Surveillance group that protects study endpoints for the trial through:

- o Scale acquisition
- o Rater qualification and training
- o Data surveillance
- o Placebo Response Training



#### **Protocol optimization**

Our Scientific Solutions group provides input into protocol design to maximize the probability of a successful study outcome. This includes enhancements to study design, population selection criteria, outcome measure selection, and study operations.



#### **Clinical Site Support**

We have a dedicated Clinical Trial Liaison team comprising advanced degreed specialists who support clinical sites with planning and recruitment of studies in psychiatry.



#### **Global Network of Sites**

We have proven processes implemented by our therapeutically aligned start-up team that ensure efficient execution of all the study's regulatory, ethical, and contractual aspects. We are familiar with the institutional requirements of sites within our network, offering a competitive advantage in your start-up.

# Meet Your Team



LeaAnn Longueira, RN Executive Director ranchise Area Lead Psychiatry and Neuroscience Rare Disease Project Management, euroscience



Richard Koenig, MPA Executive Directo Project Management, Neuroscience



Julia Forte, MSc Executive Director Neuroscience



Natalia Drosopoulou, PhD Senior Vice Presiden Global Project Management, Neuroscience



Henry Riordan, PhD Chief Development Office



Christine Moore, PhD 'ice President Scientific Solutions Neuroscience



Project Management,

Rolana Avrumson, MS

Vice President

Clinical Project

Clinical Assessment Training and Surveillance





Idil Cavus, MD, PhD /ice President, Therapeutic Area Lead, Medical Affairs, Neuroscience



Our staffing expertise and experience in psychiatric research ensure high-quality data and meaningful results. Contact us to start the conversation for your next clinical psychiatric study.