

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.

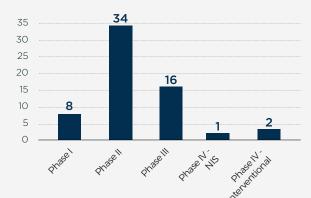
At Worldwide Clinical Trials, our experts understand the nuances associated with various psychiatric conditions, with thorough experience across a spectrum of mental health disorders.

Experience & Capabilities

Full-Service Psychiatry Experience in the Last 5 Years

Indication	Projects	Sites	Enrolled Patients
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

- → Oentral nervous system (CNS) stimulants
- → Psychedelics
- → Serotonin and norepinephrine reuptake inhibitors
- Selective p38 MAP Kinase inhibitors
- Atypical antipsychotics
- —• Neurotoxin protein
- 💳 🤊 Kappa-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 <u>Clinical</u>
<u>Assessment Training and Surveillance</u>
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, Project Management -Neuroscience; Franchise Area Lead - Psychiatry



Richard Koenig, MPA Executive Director, Project Management, Neuroscience



Julia Forte, MSc Executive Director, Project Management -Neuroscience; Franchise Area Lead - Psychedelic



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



Henry Riordan, PhDChief Development
Officer



Christine Moore, PhD Vice President, Scientific Solutions, Neuroscience



Rolana Avrumson, MS Vice President, Clinical Projects, Clinical Assessment Training and Surveillance



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