

# Industry-Leading Psychedelic Clinical Development Services

## Worldwide is the CRO of choice for sponsors paving the way for psychedelics to transform modern clinical practice in psychiatric care.

Our team is experienced with the complex procedural aspects required to ensure patient safety and to operationalize psychedelic clinical trials. We have become industry leaders in psychedelic trials, providing full clinical development plans across indications, advocating for rigorous trial designs, and setting the tone for best practices. Additionally, we are experienced in navigating regulatory and IRB interactions and the requirements and licensing for the supply chain logistics and investigator site handling of this drug class.

Worldwide has a track record of successful patient recruitment for psychedelic trials and global relationships with best-in-class investigative sites.

#### **Our Psychedelic Experience**

Worldwide has recent experience managing 22 psychedelic studies in psychiatric populations, including all phases, I through IV clinical trials conducted in Australia, the US, Canada, United Kingdom, and other European countries, across a range of psychedelic compounds and treatment models.



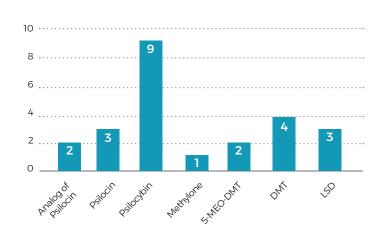
**Studies** 

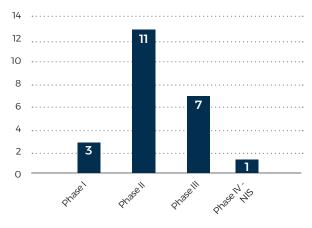




**3,490**<sup>+</sup> Participants

#### **Summary of Experience**





<sup>\*</sup>Aggregate number; does not represent unique sites

#### **Our Capabilities**



Clinical Development Planning & Regulatory Agency Interactions



Regulatory & Licensing Expertise for Controlled/Scheduled Drugs



Clinical Site Network with Appropriate Experience & "Setting"



**Complex Operational Delivery** 



Qualified Vendor Partners Accredited for IMP logistics



**Rater & Therapist Training & Support** 



**Therapist Sourcing Models** 



Protocol Design, Optimization, & Feasibility

### Clinical Consulting for Strategic & Methodological Support

Our Clinical Research Methodologies team has partnered on 11 strategic engagements for psychedelic programs, providing services such as:

- Portfolio review
- Clinical development planning
- IND-enabling activities
- Breakthrough designation
- Protocol development

These early engagement services have supported our psychedelic sponsors in leveraging the lessons learned from across this emerging field of clinical research.

#### Partner with Worldwide

Worldwide has extensive scientific and operational psychedelic experience, an in-house <u>Clinical Assessment Training and Surveillance</u> team, and proven research methodology to support your trial.

Let's talk about how we can partner on your program ----

