SIGNANT HEALTH
THE EVIDENCE GENERATION COMPANY™

Psychedelics Research Solutions

SCIENCE-LED SOLUTIONS FOR PSYCHEDELICS RESEARCH

Signant Health brings clinical science expertise and deep pragmatic experience to psychedelic drug developers. Our partnerships with industry sponsors include dozens of trials which brought novel therapeutics to market for CNS indications.

Our **unparalleled scientific expertise** and **familiarity with the evolving regulatory landscape** ensures your trials will be conducted with the **methodological rigor** required for this class of molecules to gain approvals necessary for use as therapeutic agents.

COMMON CHALLENGE AREAS IN PSYCHEDELIC RESEARCH

01 Blinding & randomization

02 Site qualification

03 Participant eligibility & recruitment requirements

04 Placebo/nocebo response & expectation bias

05 Assessment administration & scoring techniques

06 Scoring & ratings inconsistencies

HOW SIGNANT CAN HELP

RELIABLE ENDPOINT DATA

Ensure endpoint data are accurate and ready for regulatory inspection by leveraging our clinical data capture solutions and scientific advisory services.

SCIENTIFIC SUPPORT

Partner with renowned experts and key opinion leaders in CNS indications including those being conducted in MDD and other mood disorders, PTSD, anxiety disorders, grief, and OCD.

OPERATIONAL RESOURCES

Take advantage of our global reach, mature operational processes, and experienced project delivery teams, who have facilitated hundreds of trials ranging from local to multinational.

SCIENTIFIC CONSULTING FOR PSYCHEDELICS RESEARCH: **DEEPER DIVE**

Trials investigating psychedelics require the same standards of scientific and methodological precision applied to other therapeutic areas and interventions, and for which Signant is renowned. Our science and medicine team offers advisory on many aspects of trial design and operations including:

PROTOCOL DESIGN CONSULTING

- Select assessments and define schedule to measure primary endpoint
- Select an active comparator or inactive placebo condition
- Recommend methods to improve adherence and mitigate potential unblinding
- Optimize participant eligibility criteria
- Support recruitment requirements design and review

CENTRAL RATINGS

Our global network of highly calibrated central raters can provide expert clinical ratings remotely to:

- Generate accurate, reliable endpoint data
- Assess eligibility and adjudication
- Offer remote assessments to patients to reduce participation burden

SITE SELECTION & PERFORMANCE OPTIMIZATION

- Train site raters to administer assessments correctly and consistently
- Qualify sites to determine which sites have adequately adapted their environment to the needs of psychedelic trials and have the right people with the right experience

ENDPOINT RELIABILITY

- Implement placebo response mitigation training for raters and site staff to reduce influence of bias
- Measure effects over short and long timeframes
- Direct or monitor psychotherapy interventions for fidelity
- Conduct independent scoring and monitoring to evaluate fidelity of raters, therapists

DISCOVER SIGNANT SMARTSIGNALS:

A COMPREHENSIVE SUITE OF CLINICAL TRIAL OPTIMIZATION SOLUTIONS

Explore the Full Suite →

WHO IS SIGNANT HEALTH?

Signant Health is the evidence generation company. We are focused on leveraging software, deep therapeutic and scientific knowledge, and operational expertise to consistently capture, aggregate, and reveal quality evidence for clinical studies across traditional, virtual, and hybrid trial models. For more than 20 years, over 400 sponsors and CROs of all sizes - including all Top 20 pharma - have trusted Signant solutions for remote and site-based eCOA, eConsent, RTSM, supply chain management, and data quality analytics. Learn more at www.signanthealth.com.

SIGNANT HEALTH
THE EVIDENCE GENERATION COMPANY™