SIGNANT HEALTH
THE EVIDENCE GENERATION COMPANY®

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 **intimate knowledge and active participation 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.

Major challenge areas in psychedelic research

1

Functional unblinding

The psychoactive nature of psychedelic compounds creates inherent challenges in maintaining study blinding, leading to functional unblinding that can compromise endpoint assessment integrity and impact regulatory decisions.

2

Placebo response and expectation bias

Heightened expectation bias and amplified placebo/nocebo responses can significantly impact treatment outcomes, potentially masking or distorting true drug signals.

3

Inter-rater variability

Inconsistent ratings across sites due to varying rater experience with psychedelic patient presentations can compromise endpoint reliability and signal detection.

4

Complex participant selection

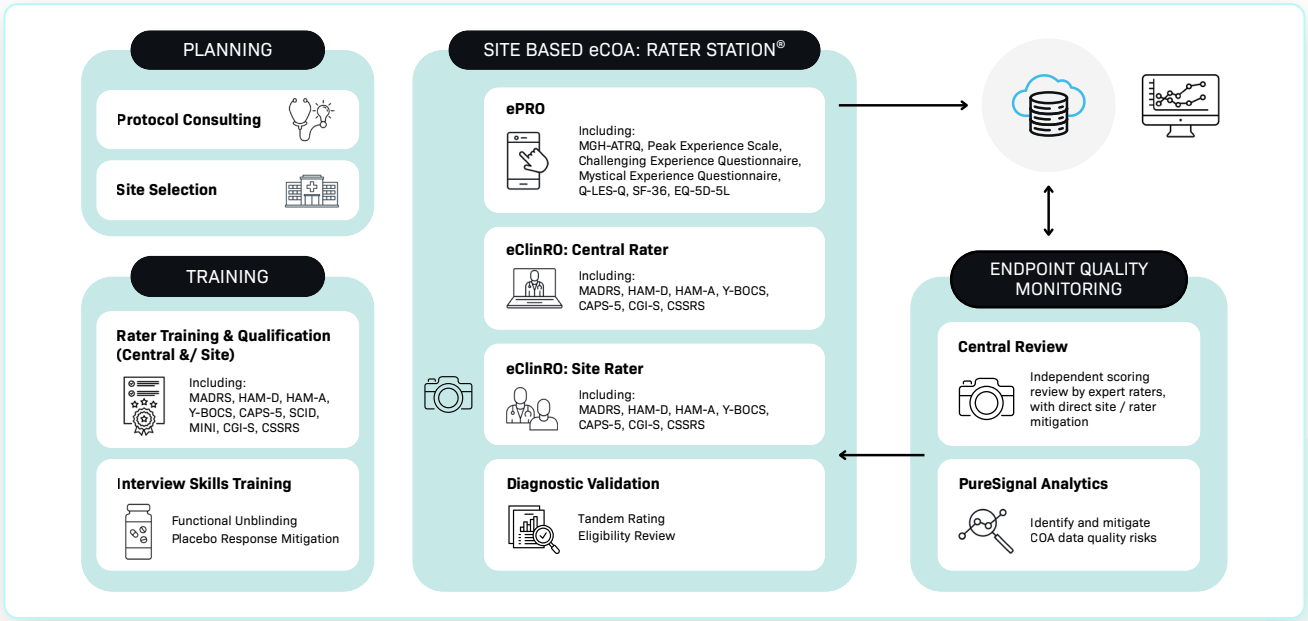
Determining appropriate study candidates requires multifactorial assessment beyond standard inclusion/exclusion criteria, accounting for treatment history, response patterns, patient reliability, and other potential data confounds to optimize signal detection.

5

Data quality and assessment consistency

Rating inconsistencies and scale administration variations can introduce noise that reduces statistical power and regulatory confidence in results.

Integrated solutions tailored to psychedelics research



Our comprehensive approach addresses the unique challenges of psychedelics research through an integrated solution framework:

PLANNING

- **Protocol Consulting:** Deep in-house clinical and scientific expertise to optimize study design for psychedelics trials
- **Site Selection:** Using proprietary quality indicators to identify and verify sites delivering high quality endpoint data suitable for psychedelic trials in multiple indications

TRAINING

- **Rater Training and Qualification (Central & Site Raters):** Specialized training on clinician-rated scales to drive standardized assessments and limit inter- and intra-rater variability
- **Interview Skills Training:** Managing functional unblinding and placebo response mitigation techniques, alongside ensuring administration fidelity

SITE-BASED eCOA: RATER STATION®

- **ePRO:** Registration-ready patient-reported outcomes including psychedelics-specific scales
- **eClinRO Assessments:** Driving standardized administration and scoring accuracy for site raters, with on-screen guidance, branching logic, edit checks, and automated scoring
- **Central Rater:** Remote administration of clinician ratings via secure telehealth platform to provide accurate endpoint data with reduced impact of functional unblinding
- **Diagnostic Validation:** Tandem Rating and Eligibility Review processes to drive accurate eligibility and enrollment and limit impact on signal detection

ENDPOINT QUALITY MONITORING

- **Central Review:** Independent scoring/administration review by expert raters with direct site/rater mitigation to drive highest quality endpoint data
- **PureSignal Analytics:** Real-time identification and mitigation of COA data quality risks throughout the study

Delivering successful eCOA: **the 4 S's**

SOLUTION

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

SCIENCE

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

SERVICE

Mature operational processes, and experienced project delivery teams who have facilitated hundreds of trials ranging from local to multinational.

SCALE

Architectural and operational capacity, with global reach from local to multinational.

Experience counts

With successful delivery of **35+ psychedelics trials**, trust Signant to provide the science, solution, service and scale to advance your psychedelics program from protocol to approval.

WHO IS SIGNANT HEALTH?

SIGNANT HEALTH
THE EVIDENCE GENERATION COMPANY

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 25 years, over 600 sponsors and CROs of all sizes – including all Top 20 pharma – have trusted Signant solutions for remote and site-based eCOA, EDC, eConsent, RTSM, supply chain management, and data quality analytics. Learn more at **www.signanthealth.com**.

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