SIGNANT HEALTH EXPERT SOLUTIONS FOR
CNS TRIAL DESIGN CONSULTING

SIGNANT HEALTH
THE EVIDENCE GENERATION COMPANY®

Designing CNS Trials for **Regulatory Success** with Signant Health

CNS trials face unique measurement challenges, including endpoints that depend on subjective clinical and performance-based assessments of mood, cognition, and thought disorders, which remain vulnerable to rater inconsistency, elevated placebo response, and baseline score inflation.

Signant Health's CNS thought leaders bring decades of hands-on clinical expertise to help sponsors develop study designs that maximize signal detection potential. Built on that foundation, our end-to-end solutions and proven operational processes protect endpoint integrity from first patient in to database lock and regulatory acceptance.

Why choose Signant Health for CNS trial design?

WORLD-CLASS SCIENTIFIC LEADERSHIP

In-house renowned psychiatrists, neurologists, and CNS clinical scientists who have pioneered assessment methodologies and shaped industry standards, drawing on over 25 years of CNS trial experience and deep institutional knowledge of the factors that drive study success.

INTEGRATED SOLUTIONS & SERVICES

Scientific consulting threaded through every element of rater training, central quality review, in-trial PureSignal Analytics services, and more, supported by our purpose-built Rater Station® technology platform, the gold standard for CNS research.

STRATEGIC PROTOCOL DEVELOPMENT

Expert guidance on patient populations, endpoint selection, inclusion/exclusion criteria, screening methodologies, and patient enrichment strategies to maximize treatment-placebo differentiation.

TRUSTED PARTNERSHIP

More than a vendor, providing long-standing collaborative relationships where our team serves as trusted colleagues throughout the study lifecycle.

Signant Health: your partner for CNS trial design services

PATIENT POPULATION STRATEGY

Defining which patients will deliver valid answers to the study's core questions

- Patient population definition with optional enrichment strategies to optimize signal detection
- Inclusion/exclusion criteria tailored to the drug's profile and proven regulatory approaches
- Patient eligibility verification services to ensure only appropriate patients are enrolled
- Site suitability assessment to focus on sites providing the highest quality data

STUDY DESIGN

Optimizing protocol design and measurement strategy to drive signal detection

- Blinded placebo run-in period considerations to mitigate baseline score inflation and identify early responders
- Strategies to decouple endpoint and eligibility measures
- Treatment arm design based on accepted regulatory approaches and program objectives
- Study setting selection (inpatient vs. outpatient), balancing data quality with real-world relevance

ENDPOINT SELECTION & IMPLEMENTATION

Developing a measurement strategy to address concepts of interest and study objectives

- Primary and secondary endpoint selection with proven regulatory and measurement science approaches to meet specific study objectives
- Assessment timing designed to capture drug effects at optimal timepoints
- Site-based vs. remote assessment approach based on endpoint complexity and compliance/regulatory requirements
- Measure development consulting

PLACEBO RESPONSE MITIGATION

Measures to proactively mitigate placebo response risks before they compromise the study outcome

- Run-in periods and enrichment approaches to identify and manage placebo responders
- Intensive tailored site and patient training to minimize expectation bias
- Rater-administered patient communication scripts designed to neutralize expectation bias and promote consistent framing of study participation
- Implementation best practices, including rater training and measurement protocols

DATA QUALITY STRATEGY

Planning for rater performance and quality oversight to ensure endpoint data reliability

- Rater qualification standards and training tailored for study endpoints
- Central review and quality monitoring strategy
- Multi-level endpoint data analytics spanning visit, rater, site and country to pinpoint intervention areas
- Performance feedback and direct-to-site remediation pathways to drive ongoing data quality

The Signant 4S advantage

SCIENCE
In-house team of renowned psychiatrists, neurologists, and CNS clinical scientists who pioneered assessment methodologies, including key opinion leaders who developed today's gold-standard rating scales

SOLUTION
Purpose-built technology platform specifically designed to address CNS assessment complexities through intelligent workflows and embedded guidance

SCALE
Proven infrastructure managing CNS trials of any scale, from targeted rare disease studies to large worldwide trials

SERVICE
Tailored operational delivery with expert teams implementing comprehensive CNS solutions throughout the entire study lifecycle

Our solutions work together

Unlock the full value of Signant SmartSignals®

- **Rater Training**
- **Rater Station**
- **PureSignal Analytics**
- **Placebo Response Mitigation**

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 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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