ADVANCING OPPORTUNITIES FOR SUCCESS IN CENTRAL NERVOUS SYSTEM CLINICAL TRIALS

GNANTHEA

Making strides towards new treatments one endpoint at a time

The clinical development process for novel therapies that treat central nervous system (CNS) diseases is scientifically and medically complex, as demonstrated by low success rates.

COMMONLY CITED CHALLENGES THAT HINDER STUDY SUCCESS INCLUDE:

- Limited ability to determine efficacy of a compound (especially in early-stage trials)
- The subjectivity of outcome measures
- Higher rates of placebo response

Signant's unrivaled, real-world scientific and medical expertise in CNS indications, coupled with innovative clinical trial technology solutions within our SmartSignals[™] evidence generation suite, encourage researchers to challenge accepted norms and outcomes in the quest to deliver novel symptomatic therapies and disease-modifying treatments.

SOLVE CNS RESEARCH CHALLENGES

Tailored to address the specific challenges and difficulties inherent in CNS studies, Signant's comprehensive solutions and scientific services help sponsors increase opportunities for signal detection by improving the quality and reliability of endpoint data in a multitude of ways throughout the course of a study:



eCOA

Dozens of common CNS outcomes assessments built into our eCOA library provide simplified electronic administration, a well-established method to eliminate errors, validity issues, and missing data associated with site-based, paper-administered COA collection.



ELECTRONIC CLINICIAN RATINGS

Proven to significantly reduce rater errors in scale administration and improve interview quality in CNS studies, the preset workflows, internal logic, and onscreen guidance within this solution help clinicians accurately collect and assess outcomes according to protocol requirements.



BLINDED DATA ANALYTICS

One of the most important elements to a successful CNS study, Signant's proactive data quality management solution leverages proprietary, cliniciandefined algorithms as well as statistical and clinical analysis to identify and mitigate risks to study data throughout the course of the trial.



COMPUTERIZED COGNITIVE ASSESSMENTS

Signant's highly sensitive and accurate battery of electronically-administered cognitive function tests is a widely used, extensively validated solution for detecting the earliest and most subtle evidence of cognitive function change in key domains (e.g. memory, attention, executive function, etc.).



SCIENTIFIC CONSULTING

Signant's in-house science and medicine team includes world-renowned experts and thought leaders in CNS indications who are instrumental in steering CNS studies to success from launch to closeout. From determining appropriate endpoints and COAs to eligibility review, rater training, and independent reviews of outcomes assessments, these experts serve as instrumental, active members of an extended study team.

SELECTION OF CNS INDICATIONS EXPERIENCE AND EXPERTISE

- Alzheimer's Dementia
- Parkinson's Disease
- Mild Cognitive Impairment
- Myasthenia Gravis
- Huntington's Disease
- Rett Syndrome
- Multiple Sclerosis
- Stroke
- Epilepsy
- ALS

- Non-Alzheimer's Dementia
- Migraine
- Rheumatoid Arthritis
- Osteoarthritis
- Diabetic Neuropathy
- Fibromyalgia
- Trigeminal Neuralgia
- Ataxia Telangiectasia
- Spinal Muscular Atrophy
- Epileptic Encephalopathies (various)

PSYCHIATRY --•

- Autism Spectrum Disorder
- Tourette Syndrome
- Generalized Anxiety Disorder
- Major Depressive Disorder
- Schizophrenia
- ADHD
- Bipolar Disorder
- Borderline Personality Disorder

AFFILIATIONS

Signant maintains active scientific and clinical relationships with leading neurological and psychiatric advocacy organizations. In collaboration with these groups and sponsors, our science and medicine team actively assists with training, designing eCOA for study-specific needs, and developing endpoint quality safeguards. A selection of memberships and relationships include:



WHO IS SIGNANT HEALTH?

SIGNANT HEALTH

Signant Health, the leader in clinical evidence generation, focuses on leveraging industry-leading software, deep therapeutic and scientific knowledge, and global operational expertise to consistently generate accurate, regulatory-compliant evidence for clinical studies across traditional, virtual, and hybrid trial models.

SIGNANTHEALTH.COM