PureSignal Analytics
CASE STUDY

SIGNANT HEALTH
THE EVIDENCE GENERATION COMPANY™

SPECIALIZED ANALYTICS ENSURE RIGOROUS ADHERENCE TO ENTRY CRITERIA TO DRIVE SIGNAL DETECTION IN PSYCHIATRY TRIAL

OVERVIEW

A pharmaceutical company partnered with Signant Health to implement the PureSignal Analytics solution in a Phase II mood disorder trial where baseline score inflation and patient eligibility presented a significant challenge for the study. Signant's specialized analytics enabled systematic detection of potential eligibility issues and facilitated targeted site interventions to protect endpoint data reliability and quality.

TRIAL SUMMARY

Study Phase: II

Therapeutic Area: Psychiatry

Indication: Mood Disorder

Patient Population: Adult

Geographic Scope: 1 country

Number of Sites: 50

Number of Patients: 250+

Number of COAs: 10

Languages: 2

CHALLENGES

1. Mood disorder trials frequently face challenges associated with **baseline score inflation** and the inclusion of patients who may not fully meet **diagnostic criteria for study entry.**

2. Such issues can have a significant, **adverse impact on signal detection** and study outcomes.

3. The sponsor needed a robust, scientific approach to ensure enrolled patients accurately met the **protocol-specified criteria** for a major depressive episode **(MDE)**, while maintaining efficient study progress for patient recruitment.

SOLUTIONS

1. To facilitate rigorous adherence to the study's patient eligibility and inclusion criteria, Signant deployed its **PureSignal Analytics** solution to the study.

2. Using **proprietary algorithms** to map clinical outcome assessment (COA) responses to the Diagnostic and Statistical Manual of Mental Disorders (DSM-5) MDE criteria, the analytics solution enabled **continuous monitoring of patient screening patterns** across all study sites and raters in real-time.

3. When potential baseline inflation risks were detected, the solution provided **targeted rater- and site-level interventions** to better control and optimize patient recruitment throughout the study.

RESULTS

- The purpose-built algorithms identified that approximately 20% of screened patients were associated with **diagnostic concerns around their eligibility**.

- To mitigate risks to study data, the solution facilitated rapid interventions including **targeted rater retraining, rater replacement** and, where necessary, **full recruitment holds.**

- One site was ultimately **discontinued** due to persistent patterns of screening patients with questionable MDE diagnosis despite multiple remediation attempts. These interventions ensured optimal site performance levels across the whole study.

- This **systematic approach to patient eligibility and recruitment** demonstrated the value of specialized analytics in maintaining rigorous patient inclusion standards, thereby protecting the **integrity and reliability of study endpoints** and limiting inflation of placebo response.

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**.