

CASE STUDY

Signant's Specialized Analytics Protect Signal Detection by Ensuring Rigorous Patient Eligibility in Mood Disorder Trial

TRIAL SUMMARY

Study phase: 2

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

OVERVIEW

A pharmaceutical company partnered with Signant Health to implement the PureSignal Analytics solution in a phase 2 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.

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.
- ④ It enabled immediate identification, investigation, and **mitigation of COA data concerns** during study conduct.

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.

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