

CASE STUDY

Signant's PureSignal Analytics Drives Successful FDA Approval for Psychiatric Treatment

OVERVIEW

A pharmaceutical company trusted Signant Health to implement a data-driven recruitment optimization strategy for their phase 3 psychiatry trial by leveraging sophisticated analytics. Signant's PureSignal Analytics solution enabled systematic optimization of patient recruitment by identifying and prioritizing sites demonstrating the highest quality clinician ratings, supporting the successful outcome of the trial.

TRIAL SUMMARY

Study phase: 3

Therapeutic area: Psychiatry

Patient population: Adult

Geographic scope: 2 countries

Number of sites: 45+

Number of patients: 500+

Number of COAs: 8

Languages: 2

CHALLENGES

- ① The trial needed to meet its patient **recruitment goals while ensuring optimal signal detection potential** through high-quality endpoint data collection.
- ② Traditional recruitment approaches that focus primarily on enrolment speed and site capacity might not always account for **important variations** in clinical outcome assessment **(COA) data quality** across the study sites.
- ③ To ensure primary endpoint reliability and to optimize signal detection potential, the sponsor sought a data-driven strategy to drive **patient recruitment** toward sites demonstrating the **highest standards** of clinician reported-outcome **(ClinRO) assessment and data quality**.

SOLUTIONS

- ① Signant implemented its **PureSignal Analytics** solution to assess clinician rating quality across all the study sites. The solution deployed proprietary custom **analytics tailored to the study endpoints** to evaluate site performance in relation to ClinRO measures.
- ② Purpose-built algorithms based on specific **endpoint quality indicators** systematically monitored and compared the ClinRO data being generated across all the study sites.
- ③ It was combined with a **gated recruitment process** to strategically direct patient enrollment to sites with superior assessment data quality.
- ④ It enabled immediate identification, investigation, and **mitigation of COA data concerns** during study conduct.

RESULTS

- PureSignal Analytics successfully identified the highest-performing sites based on comprehensive **endpoint data quality metrics**.
- It allowed the sponsor to optimize the allocation of new patients towards sites consistently collecting high-quality endpoint data. By prioritizing and **driving recruitment at top-performing sites**, the strategy helped **maximize the potential for signal detection** while maintaining efficient study progress.
- The study was successfully completed, with quality data supporting the sponsor's regulatory submission and ultimately resulting in FDA approval. This outcome demonstrated the **value of leveraging advanced analytics** to optimize both **recruitment efficiency and scientific reliability** in clinical trials.

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.