PureSignal Analytics
**CASE STUDY**

SIGNANT HEALTH
THE EVIDENCE GENERATION COMPANY™

# ANALYTICS INSIGHTS IMPROVE QUALITY OF ASSESSMENT ADMINISTRATION IN A SCHIZOPHRENIA TRIAL

## OVERVIEW

A global pharmaceutical sponsor leveraged Signant Health's PureSignal Analytics solution in a Phase III schizophrenia trial involving a complex, clinician-rated primary efficacy outcome measure that required careful administration to ensure reliable scoring. Signant's analytics solution enabled early identification of at-risk administration patterns and successfully implemented targeted interventions to improve endpoint data quality.

## TRIAL SUMMARY

**Study Phase:** III

**Therapeutic Area:** Psychiatry

**Indication:** Schizophrenia

**Patient Population:** Adult

**Geographic Scope:** 1 country

**Number of Sites:** 45+

**Number of Patients:** 250

**Number of COAs:** 4

**Languages:** 1

## CHALLENGES

1. The Phase III study involved a challenging patient population and administration of a complex clinical outcome assessment (COA), the **Positive and Negative Syndrome Scale (PANSS).**

2. To ensure endpoint data reliability, **proper administration** of the assessment was crucial whereby raters spent sufficient time to accurately elicit the information required to **confidently score** the primary efficacy outcome measure.

3. With trial design spanning across many sites and raters, the sponsor needed a systematic and rigorous approach to identify potentially problematic interviews including **unusual assessment durations** that might indicate data quality risks.

## SOLUTIONS

1. Signant Health implemented its **PureSignal Analytics** solution to detect and address potential data quality issues across ClinRO administration and scoring.

2. It included specific analytics to evaluate **PANSS duration patterns** across sites, compare individual site and rater performance against established benchmarks, and identify interviews that could indicate **inadequate assessment quality**.

3. The solution was deployed to rapidly uncover potential COA administration errors and facilitate **targeted remediation,** including rater contact and retraining, where needed.

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## RESULTS

- Based on previous PANSS completion data, a benchmark duration for appropriate administration was 40 minutes. Against this standard, the solution successfully **identified problematic sites and raters** that completed PANSS assessments in significantly less time than the expected duration, thus **requiring corrective actions.**

- One site, with an average baseline interview duration of only 22 minutes, was ultimately **discontinued** due to serious data quality concerns. In other cases, **retraining** was provided to individual raters whose interview duration was significantly below the established benchmark. As a result, only those who improved sufficiently after the remediation continued with the study, enabling the sponsor to actively maintain **reliable endpoint data** collection throughout the trial.

## 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**.