

CASE STUDY

Signant's PureSignal Analytics Reveals Data Quality Issues, Supporting No-Go Decision for Neurology Program

OVERVIEW

A pharmaceutical sponsor partnered with Signant Health to perform post-hoc analysis of their phase 2 neurology trial that showed inconsistent efficacy signals. Signant's PureSignal Analytics solution provided detailed investigation of contradictory findings between site and central raters, delivering evidence-based insights to support the sponsor's go/no-go pipeline decision-making.

TRIAL SUMMARY

Study phase: Phase 2

Therapeutic area: Neurology

Participant population: Adults

Geographic scope: 1 country

Number of sites: 20+

Number of patients: 90+

Number of COAs: 8

Languages: 1

CHALLENGES

- ① The sponsor faced a difficult R&D decision-making challenge when the phase 2 trial results showed **contradictory efficacy signals between site and central raters** for key clinical outcome assessments (COAs), including the primary endpoint.
- ② While site rater data suggested treatment-placebo separation, central rater assessments failed to demonstrate this effect.
- ③ This discrepancy created **significant uncertainty around the true treatment effect** and complicated the sponsor's ability to make confident go/no-go decisions for their drug development program.

SOLUTIONS

- ① Signant performed a comprehensive **post-hoc analysis** using its **PureSignal Analytics** solution to investigate the source of discrepancy between site and central rater findings.
- ② PureSignal Analytics is a **specialized solution** that deploys proprietary algorithms specifically **tailored to study endpoints** to identify and interpret COA administration and scoring issues that might impact the study's ability to **distinguish treatment intervention effects**.
- ③ Using purpose-built analytics to examine scoring patterns, inter-rater variability, and site-level trends that might **explain the contradictory results**, the solution provided data-driven insights to support the sponsor's development program decision-making.
- ④ It enabled immediate identification, investigation, and **mitigation of COA data concerns** during study conduct.

RESULTS

- The comprehensive post-hoc analysis uncovered **one investigative site with highly problematic data** patterns. When data from this site was **excluded from analysis**, the apparent treatment-placebo separation in the site rater data was no longer evident, aligning with the central rater findings.
- This insight suggested that the original positive signal was driven by data quality issues rather than true treatment effects, leading to Signant's **recommendation of a no-go decision** to the sponsor.
- This analysis demonstrates the value of specialized, clinically-driven endpoint analytics in supporting **evidence-based decisions** and potentially avoiding costly late-phase failures for drug development programs.

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