PureSignal Analytics
**CASE STUDY**

SIGNANT HEALTH
THE EVIDENCE GENERATION COMPANY™

# ADVANCED ANALYTICS AND CENTRAL REVIEW ENHANCE ASSESSMENT QUALITY IN A PIVOTAL PHASE III TRIAL

## OVERVIEW

A global pharmaceutical company partnered with Signant Health to leverage the PureSignal Analytics solution in a large-scale Phase III trial involving hundreds of sites and raters worldwide. The trial included multiple clinician-reported outcome measures, including the primary endpoint. Signant's solution combined proprietary in-trial analytics with central review of audio recorded rating interviews by expert raters, to identify and mitigate assessment quality risks through targeted interventions, driving highest quality clinical outcome assessment data.

## TRIAL SUMMARY

**Study Phase:** III

**Therapeutic Area:** Neurology

**Patient Population:** Adult

**Geographic Scope:** 14 countries

**Number of Sites:** 200+

**Number of Patients:** 1,500+

**Number of COAs:** 6

**Languages:** 12

## CHALLENGES

1. This large Phase III global neurology trial faced endpoint data quality monitoring challenges due to the **large number of sites and raters** involved in administering and scoring multiple **complex** clinician-reported outcome **(ClinRO) assessments.**

2. Maintaining **correct administration** procedures and **accurate scoring** throughout the trial was essential to achieve endpoint reliability and optimize signal detection potential.

3. The sponsor needed **clinical confidence** through a comprehensive and robust approach that ensured **high-quality endpoint data** collection across all of the study locations.

## SOLUTIONS

1. Signant implemented **PureSignal Analytics** alongside **independent central review** of audio recorded rating interviews to provide comprehensive, real-time endpoint data quality oversight.

2. **Proprietary analytics** continuously monitored administration procedures and scoring patterns to detect **potential risks to ClinRO data** quality and reliability in real-time.

3. In conjunction, independent expert review of assessment recordings allowed **immediate feedback** to site raters when **administration or scoring errors** were identified.

4. This integrated approach enabled rapid detection of problematic assessment patterns and facilitated timely delivery of **corrective interventions** where required.

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## RESULTS

The deployment of Signant's PureSignal Analytics and Central Review solutions proved vital in actively maintaining high-quality ClinRO data throughout the study.

- Using proprietary algorithms to identify raters and sites accumulating administration and scoring errors, the solution successfully prioritized those requiring **enhanced remediation and retraining.** Most retrained raters showed significant improvement following these interventions, while a small number who did not demonstrate adequate improvement were replaced by the sponsor to protect the integrity of study data.

- Through **proactive identification and mitigation** of ClinRO data quality risks, the sponsor was able to achieve reliable and **high quality endpoint data collection** throughout the trial. The study was successfully completed, demonstrating the value of a **systematic and integrated approach** to endpoint data quality monitoring and mitigation in large, complex global trials.

## 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**.