PureSignal Analytics
CASE STUDY

SIGNANT HEALTH
THE EVIDENCE GENERATION COMPANY™

ANALYTICS INSIGHTS ALLOW EARLY IDENTIFICATION AND MITIGATION OF FRAUDULENT DATA IN A GLOBAL TRIAL

OVERVIEW

A global biopharmaceutical company partnered with Signant Health to provide PureSignal Analytics solution for a Phase II clinical trial involving a large number of sites dispersed across many countries. The trial included both clinician-reported outcomes (ClinRO) and patient-reported outcomes (PRO) as key endpoints, with Signant's analytics solution enabling proactive identification of data quality concerns including fraudulent data patterns, and implementation of swift interventions.

TRIAL SUMMARY

Study Phase: II

Therapeutic Area: Dermatology

Patient Population: Adult

Geographic Scope: 10 countries

Number of Sites: 110

Number of Patients: 350

Number of COAs: 10+

Languages: 10

CHALLENGES

1. This trial faced data quality monitoring challenges due to its design involving a relatively **small number of patients** per site spread across a **large number of locations.**

2. With rapid recruitment occurring simultaneously at multiple sites, it was difficult for standard monitoring methods to **detect subtle patterns** that might indicate **data quality risks**.

3. Due to the number of sites and raters, **driving low inter-rater variability** to achieve standardized and consistent scoring was important for ensuring high quality endpoint data.

4. The sponsor needed a **robust approach to monitor** both clinician-reported and patient-reported outcomes in **real-time**.

SOLUTIONS

1. Signant implemented **PureSignal Analytics, a specialized, end-to-end solution** to monitor clinical outcome assessment (COA) data quality across all study sites and mitigate issues in a timely manner.

2. The solution deployed **proprietary analytics** to detect potential issues, outliers and anomalies for both ClinRO and PRO data.

3. Ongoing clinician-driven reviews included meta-data analysis and interpretation of potential quality concerns identified, allowing **evidence-based recommendations** for intervention.

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

RESULTS

The solution proved instrumental in ensuring endpoint data quality and reliability.

The solution successfully identified one highly problematic site showing clear indicators that suggested potential **data fabrication.** Detailed analysis of the site's PRO data revealed suspicious behaviors, including unexpected and improbable completion patterns. The site with suspected fraud was **halted from further recruitment** and immediately escalated for formal investigation by the clinical research organization (CRO) responsible for trial oversight.

By identifying and addressing these concerns early in the process, the sponsor was able to **prevent further propagation of flawed data** compromising study data quality. The combination of advanced analytics with expert in-house clinician interpretation and mitigation highlighted the **value of a comprehensive and proactive approach** to COA data quality in safeguarding the integrity of study endpoints.

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**.