SIGNANT HEALTH
THE EVIDENCE GENERATION COMPANY™

Case Study | Endpoint Quality & Reliability Solutions

CNS TRIALS SUCCEED WITH SUPPORT FROM SIGNANT'S COMPREHENSIVE ENDPOINT QUALITY SOLUTIONS

A Japanese pharmaceutical company's phase 3 and long-term extension trials achieved successful outcomes with help from Signant Health's comprehensive, expert-supported data quality management solutions.

OVERVIEW:

A Japan-based, global pharmaceutical development company engaged Signant Health to provide clinical research endpoint quality solutions and services for its phase 3 and long-term extension trials investigating a treatment for a substance use disorder. The trials, conducted across dozens of sites in Japan, included numerous complexities related to the quantity and nature of the protocols' clinical outcome assessments (COAs) and rating instruments. Signant leveraged its **proven technology solutions, leading clinical and eCOA science expertise, as well as data quality management services** to help the sponsor optimize endpoint reliability throughout the duration of the trials.

TRIAL SUMMARY:

- **Study Phase:** III, long-term extension
- **Therapeutic Area:** CNS
- **Patient Population:** Adults
- **Number of Patients:** 1,000
- **Number of Sites:** 80
- **COAs:** 15
- **Countries:** 1 (Japan)
- **Languages:** 1

CHALLENGES:

01 With 240 raters administering several complex instruments across 80 sites, the studies were at increased risk for errors or unwanted variability that could introduce noise and negatively impact signal detection.

02 Several instruments and assessments, including those supporting the primary endpoint, were not frequently used in Japan at the time the trials were conducted and thus unfamiliar to most raters.

03 Some raters would not be able to attend a live training but needed to receive certification in proper assessment administration and scoring technique to be able to participate in the trials.

SOLUTIONS:

01 Signant's COA science experts performed scale acquisition, translation, and distribution services, carefully navigating scale licensing and permissions with their respective copyright owners while ensuring accuracy and on-time delivery.

02 Signant combined several solutions and strategies to develop a custom, standardized, and localized rater training program for each COA, designed to ensure optimal data quality. Resources that supported the creation and execution of the training programs included; Signant SmartSignals Rater Training & Qualification software solution, on-staff clinical experts, scale owners and authors, and local Japanese clinical experts.

To complete a program successfully, raters participated in didactic presentations using case examples, guided discussions, and workshops. Signant also produced a custom training video available on-demand for clinician-raters who could not attend live training.

03 Ongoing endpoint reliability management solutions – including audio monitoring and independent expert review of the key scale – further ensured accuracy of COA data.

RESULTS:

The trials generated high-quality, reliable evidence that helped support regulatory review and approval of a medication to treat a substance use disorder.

Signant's comprehensive scale management, rater training, clinical science consulting, and data quality monitoring solutions meant the sponsor could be confident in a well-conducted study that properly tested the research drug.