SIGNANT HEALTH
THE EVIDENCE GENERATION COMPANY™

CASE STUDY:

SIGNANT SMARTSIGNALS RATER TRAINING AND CENTRAL RATING SERVICES

OVERVIEW:

To optimize signal detection in a pivotal, regulatory efficacy trial, a global pharmaceutical company needed to ensure that the primary endpoint was measured consistently using clinician ratings of abnormal, involuntary movements in patients with tardive dyskinesia (TD). This important movement disorder trial had a successful outcome and led to FDA product approval.

TRIAL SUMMARY:

Study Phase: II/III

Therapeutic Area: Neurology

Patient Population: Adults, aged 18-75

Primary endpoint: Abnormal Involuntary Movement Scale (AIMS) score

Number of Patients: 100+

Number of Sites: 35+

Countries: USA & Europe

CHALLENGES:

01

STANDARDIZE THE CLINICIAN ASSESSMENT OF THE PRIMARY ENDPOINT (AIMS)

The sponsor wanted to ensure that the test procedure for the AIMS was consistently delivered across all investigational sites to improve the trial's signal detection power by minimizing variability in scoring due to differences in test procedures or administration.

02

ELIMINATE VARIABILITY IN AIMS SCORING DUE TO SUBJECTIVE DIFFERENCES BETWEEN RATERS

The clinical ratings in this trial (AIMS) served as measures of the primary efficacy endpoint. As such, the sponsor wanted to minimize any differences in scoring between raters that could affect the ability of the trial to demonstrate treatment-related effects.

03

ELIMINATE POSSIBLE INTRODUCTION OF BIAS IN ASSESSMENT RATINGS DUE TO TIME ON TREATMENT

To maximize trial power, the sponsor wanted to eliminate any possibility that the time on treatment, or other factors such as side effect profile, would have an influence on the scores provided by raters.

SOLUTIONS:

01 RATER TRAINING TO ENSURE CONSISTENT TEST CONDUCT

The sponsor leveraged Signant Health's Rater Training and Qualification services, delivered by in-house expert raters, to ensure that all investigators were able to deliver a consistent, standardized set of tests for AIMS assessment. Rater training is an essential component of trials, including for subjective clinician ratings as important primary or secondary endpoints, to reduce inter- and intra-rater variability and improve the sensitivity of the trial endpoint to detect treatment-related differences.

02 LEVERAGE INDEPENDENT CENTRAL RATERS TO PROVIDE ACCURATE, CONSISTENT ENDPOINT SCORES

The primary endpoint was the change in AIMS score from baseline to week 12. This was assessed by two blinded central video raters who were movement disorder experts. These central raters performed the AIMS evaluation based on a video recording of the test procedure conducted at each investigational site. For each item within the AIMS measure, both raters provided scores and a consensus AIMS rating was agreed upon, ensuring optimal accuracy and precision.

03 PERFORM RATINGS IN A BLINDED MANNER TO ELIMINATE POTENTIAL SOURCES OF RATER BIAS

Video recordings were blinded with respect to treatment, visit number, investigational site, and recording date. By doing so, potential sources of rating bias were eliminated, including length of time on treatment, previous patient scores, and the potential of side effects to provide a suggestion of treatment group. This ensured that the trial was optimized to assess treatment-related effects on unwanted involuntary movements, ultimately leading to a successful outcome and FDA market approval.

ABOUT SIGNANT HEALTH

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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 20 years, over 400 sponsors and CROs of all sizes – including all Top 20 pharma – have trusted Signant solutions for remote and site-based eCOA, eConsent, RTSM, supply chain management, and data quality analytics. For more information, please visit www.signanthealth.com.