SIGNANT HEALTH
THE EVIDENCE GENERATION COMPANY®

CASE STUDY

Digital Health & Clinical Ratings Quality Management Solutions Facilitate Regulatory Success in Myasthenia Gravis Trial

OVERVIEW

A global sponsor partnered with Signant Health to execute a complex global Phase 3 study evaluating a treatment of generalized myasthenia gravis (gMG). The study required comprehensive digital health and data quality management solutions to optimize endpoint reliability. Signant's electronic clinical outcome assessment (eCOA) platform, rater training programs, and COA data analytics solutions proved instrumental in the trial's success.

TRIAL SUMMARY

Study phase: Phase 3

Therapeutic area: Neurology/ Autoimmune

Participant population: Adults

Number of patients: 210

Number of sites: 90

COAs: 11 assessment scales

Countries: 19

Languages: 18

CHALLENGES

1. **Complex, multilingual assessment requirements:** The global study required comprehensive assessment of 11 different outcome measures across 18 languages and cultures, including both patient-reported outcomes and clinician-reported outcomes, plus integration of wearable device data for continuous physiological monitoring.
2. **Standardized rater training across global sites:** With more than 200 raters across 90 sites in 19 countries administering and scoring complex myasthenia gravis-specific assessments, the study faced significant risk of unwanted data variability that could compromise signal detection. Many assessments were specialized scales requiring expert knowledge of neuromuscular conditions.
3. **Real-time data quality management:** The trial's multi-year duration and global scope required sophisticated monitoring to proactively identify data quality issues, ensure regulatory compliance, and maintain study integrity throughout multiple treatment periods.

SOLUTIONS

1. **Comprehensive eCOA platform with multilingual support:** Signant deployed its robust eCOA platform with electronic patient diaries, site-based assessments with built-in scoring algorithms, seamless wearable device integration, and dynamic language switching across 18 languages. The system included offline capability to ensure data capture in areas with limited connectivity and real-time data validation.

2. **Specialized rater training and certification program:** Signant developed a comprehensive training program featuring 11 didactic presentations, 7 licensed training videos, interactive quizzes for key scales, and 6 virtual investigator meetings. The program included specialized QMG scale certification with mock interview assessments, co-rating requirements, and remediation processes, delivered through a protocol-specific Learning Management System with 24/7 access and progress tracking.

3. **Blinded data analytics and risk-based monitoring:** Signant implemented a sophisticated COA data analytics program with dozens of study-specific quality indicators, along with real-time statistical monitoring and automated detection of outlying variability. The system provided risk stratification dashboards, targeted site interventions based on quality metrics, and comprehensive monthly assessment and reporting to ensure ongoing data integrity.

RESULTS

Signant's comprehensive approach to data quality excellence ensured standardized scale administration across all sites and languages, reduced inter- and intra-rater variability through systematic training, and provided real-time quality control with proactive issue resolution. This robust data capture and data quality monitoring framework helped the sponsor demonstrate clinically meaningful treatment effects, meeting both primary and key secondary endpoints, and positioning it for regulatory submission and success.

WHO IS 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 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**.