



CASE STUDY: MASTERING AGITATION ENDPOINTS WITH ASSESSMENT EXPERTISE

— background

CRC supported a phase III trial evaluating a novel formulation for the treatment of agitation associated with dementia with the following rater services: procurement / licensing of 11 scales in 2 languages; development of rater materials; rater qualification, training, and certification; algorithmic rater surveillance.

— CRC solutions

CHALLENGE

Inadequate Existing Training Resources for Study Scales

Ensuring Rater Engagement During Training

Training & Certifying 45 Raters at 16 Sites in 6 Months

Site Personnel Changes

Minimizing Rater Drift

Maintaining Rating Quality

SOLUTION

Video vignettes demonstrating varying levels of agitation severity across key domains.

Developed a training program with live video, interactive methods, and periodic quizzing.

Designed a rater training and certification program to meet the sponsor's start-up timeline.

Coordinated with project management to train and certify additional site personnel, sometimes within 24 hours.

Conducted monthly refresher trainings based on ongoing rater surveillance and site feedback to address issues and trial progress.

Held weekly rater surveillance meetings to review algorithmic data together with sponsor.

— outcome

KEYS TO SUCCESS

Custom Rater Training Materials & Efficient Training / Certification Process

Effective Surveillance via Algorithms, Minimizing Labor & Refining Retraining

OUTCOME

Post-hoc analysis demonstrated high levels of correlation between agitation scales and clinical outcome measures. Additionally, rater surveillance and remediation efforts led to improvements in rating quality and consistency throughout the course of the study.

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