



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.

LEARN MORE



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