IN-STUDY RATINGS SURVEILLANCE: ITS IMPACT ON DATA QUALITY IN GLOBAL AD TRIALS

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Introduction: The Alzheimer’s Disease Assessment Scale-Cognitive subscale (ADAS-Cog) is the most commonly used primary efficacy measure in Alzheimer’s disease (AD). Earlier research has demonstrated considerable variability in how raters have been trained to administer and score the ADAS-Cog in clinical trials. An In-Study ratings surveillance program, which identifies rater errors in scale administration and scoring in trial, and remediates raters when those errors occur, is one way to potentially minimize both error and drift.

Aim: We assessed the program's impact on overall data quality in global AD trials.

Methods: After having been trained and certified to rate the ADAS-Cog in two separate, multi-national AD clinical trials, all raters' performance on scale administration and scoring was assessed by worksheet review at two time points - baseline and 1 year.

Results: 780/2427 (32%) of baseline worksheets required a contact. There was a statistically significant decrease in the number of assessments requiring a contact at one year 78/1004 (8%), p< 0.001. When evaluated separately, each trial demonstrated a similar, statistically significant decrease over time. For all geographical regions combined there was a 76% decrease in the number requiring contact after assessment at one year relative to the number of contacts required at baseline (range: 72-86%). This pattern, seen across all geographical regions, was largest in Latin America, and smallest in the United States.

Conclusion: A customized In-Study ratings surveillance program can significantly reduce rater ADAS-Cog scoring and administration errors and rater drift over time. Its implementation in future global dementia trials warrants consideration.