Enriched Rater Training and In-Study Ratings Surveillance: A Synergy?

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INTRODUCTION

Decreased placebo drug separation in multi-national clinical trials in CNS disorders, including Alzheimer's disease (AD) is a cause for great concern (Yang, Cusin and Fava, 2005; Kemp, Schooler and Kalali, 2008). One potential means of addressing this in global AD trials is the implementation of an In-Study ratings surveillance program. Such a program can provide ongoing monitoring of data quality, and provide timely remediation to raters when they deviate from scale administration and scoring conventions. Additionally, with the increased globalization of AD clinical trials, sponsors are faced with multiple challenges: identifying raters with relevant clinical as well as clinical trial experience, finding raters who are familiar with the efficacy instruments, and overcoming documented variability in scale administration and scoring training that raters may have previously received (Miller, Bartko and Connor, 2008). We report on the effects of combining a program that provides enriched training for less experienced raters with an In-Study ratings surveillance program on Alzheimer’s Disease Assessment Scale – Cognitive subscale (ADAS-Cog) data quality, when utilized in two separate multi-national AD clinical trials.

AIM

Adequately identifying, training and certifying potential investigators, and ensuring that they properly administer and score the efficacy instruments over the course of global AD clinical trials often proves challenging. This is particularly the case with the ADAS-Cog, the most commonly used primary efficacy measure.

Previous research has shown that when less experienced raters are given enriched pre-investigators’ meeting training previously described on the ADAS-Cog, they certify to participate at rates equivalent to their more experienced colleagues (Miller, Samuelson, Foulks and Moya, 2009). We evaluated the impact of an In-Study ratings surveillance program – which identifies and remediates rater errors in scale administration and scoring when they occur – on the raters’ subsequent performance in the course of a clinical trial. The in-study performance of those less experienced raters who required and received the enriched pre-investigators’ meeting training was compared to that of their more experienced colleagues.

METHODS

Two separate, multi-national Alzheimer’s disease clinical trials that employed enriched pre-investigators’ meeting (IM) training and a customized in-study ratings surveillance program were evaluated to assess both programs’ impact. Less experienced potential raters received enriched training on the ADAS-Cog in advance of the Investigators’ Meeting (IM) and had to demonstrate scoring competency on the scale prior to attending the IM. Once at the IM, all raters (those who required enriched training and their more experienced counterparts who did not) received extensive didactic training on proper ADAS-Cog administration and scoring, and also had to demonstrate their competence to rate by successfully watching and scoring a video of the scale being administered to a patient. Rater performance (proper administration and scoring) was assessed by a calibrated Clinician who reviewed ADAS-Cog worksheets for errors at 2 visit time points – baseline and 1 year – for each patient. Error type was characterized as either clerical in nature or reflective of a deviation in the scale administration and/or scoring conventions. In both cases, raters were remediated when an error was identified. Raters received a “clarification” contact, when the error was clerical in nature, and a “support” contact, when the error reflected improper or aberrant administration and/or scoring technique.

RESULTS

214/1131 (19%) of certified, participating raters required enriched training, while 917 (81%) did not. At each time point assessed, there was no statistically significant difference between the groups regarding the mean number of support contacts each rater required, nor in the distribution of the number of required support contacts in each group (Graph 1). Both groups required significantly fewer support contacts at 1 year than at baseline.

CONCLUSION

The trend toward clinical AD trials focusing on potential disease modifying agents has resulted in trials that are longer. As a result, the potential for an expanded rater pool exists and the likelihood of rater drift increases. A customized In-Study ratings surveillance program can both identify instances where raters deviate from proper ADAS-Cog administration and/or scoring technique, and by remediating raters in question, can effectively decrease the likelihood of errors recurring over the course of an AD clinical trial. Enriched training enabled less experienced raters to perform comparably to their more experienced peers. Therefore, both programs warrant consideration in AD trials.

REFERENCES