

Title

Comparison of PANSS Logical Error Rates using eCOA vs. Paper Data Collection

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Methodological Question Addressed

Can Electronic Clinical Outcome Assessment (eCOA) Reduce Errors Rating the PANSS?

Introduction

We have previously shown that logical inconsistencies in scoring the PANSS during screening are predictive of errors post baseline (Daniel, Lee, Forbes, et al, 2016) and are associated with increased placebo response (Kott, Lee, Forbes et al, 2016). Electronic clinical outcome assessment (eCOA) systems have the potential to improve data quality by detecting errors and providing investigators the opportunity to make corrections while still with the patient prior to data transfer to the EDC. We hypothesized that electronic “edit checks” of this kind would result in a lower rate of logical inconsistencies in rating the PANSS compared to historical controls using conventional paper data collection.

Methods

Dataset consisting of 81,752 PANSS assessments was pooled from 25 double blind placebo controlled schizophrenia clinical trials. Depending upon the means of PANSS data collection the data were divided into paper collection or eCOA collection. The data were queried for the presence of the most common within PANSS logical inconsistencies and the presence of these within PANSS inconsistencies was compared between the paper and eCOA collected data using the chi2 test.

Results

In the overall dataset 11,790 visits with at least 1 within PANSS inconsistency were identified. Most affected visits (89.4%) had 1 within PANSS discrepancy, 9.6% had 2 discrepancies and 1% suffered from 3 discrepancies. A significant difference ($\chi^2(1) = 215$; $p < 0.001$) in the presence of within PANSS discrepancies was observed between the paper collection (14.4%) and the eCOA collection (6.6%).

Discussion

eCOA data collection had significantly lower error rates of PANSS logical consistencies compared to paper collection. Utilizing “edit checks” eCOA has the potential to educate raters and prevent errors that may represent misunderstanding or misuse of scale rules and have been shown to be associated with higher placebo response.

References

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Disclosure

Both authors are full time employees of CRF Bracket