

Evaluating the Impact of Rater Change on PANSS Score Change: An Item Level Analysis

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SUBMISSION DETAILS

What is the Methodological Question Being Addressed? How rater change impacts PANSS item-level score changes

Introduction The PANSS is a commonly employed scale to assess symptoms of schizophrenia requiring clinical evaluation of data collected through clinical interviews with participants and caregivers. This poster explores the impact of PANSS rater change on PANSS item-level variability by comparing score changes between ratings made by the same rater vs. ratings made by different raters. Overall median score change was significantly different between the two groups. The majority of PANSS items showed susceptibility to rater change as evidenced by a significantly higher variability in scores. Only eleven PANSS items resulted as having non-significant score changes even in instances where the raters were different at subsequent visits. This research carries important implications for sponsors considering using the PANSS for inclusionary and/or endpoint assessment in clinical trials. It also highlights the need for robust rater training and endpoint reliability programs in clinical trials.

Methods PANSS data were evaluated from 4 multi-national, double-blind, placebo controlled clinical trials in schizophrenia.

In each of the 4 multi-national trials, raters were trained and certified on the PANSS. All PANSS raters met experience criteria (educational degree and scale) for the respective protocol and were qualified on a PANSS scoring exercise and interview skills assessment prior to administering the scale in a study. There were 350 distinct raters who administered the PANSS at a Screening visit with 10,100 post-screening visits. Of the post-screening visits, 93.0% (9,397) had the same rater from Screening and 7.0% (703) had a different rater.

In this analysis, PANSS score change for each item was compared between groups (with rater change and without rater change).

Results A Shapiro-Wilk test for normality on the PANSS score change found the distribution to be significantly different from a normal distribution (all $ps < 0.0001$). A Mann-Whitney test was conducted for each item to determine the influence of rater change on score change.

Conclusion Overall, 19 out of 30 of the PANSS Items were significantly affected by rater change from previous visit. The three most significant items impacted were those that relied on observation during the interview, clearly highlighting how idiosyncratic evaluation can impact PANSS ratings. There appear to be a number of PANSS items which are more resilient to rater change (Table 4). Seven of these eleven items are based, to an extent, on reports from caregivers. This suggests that items evaluated with consideration for "external" reports may be less subject to variation due to

rater change.

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Keywords

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Guidelines I have read and understand the Poster Guidelines

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