

eCOA ADMINISTRATION OF THE PANSS MINIMIZES ERRORS TO IMPROVE SIGNAL DETECTION

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THE METHODOLOGICAL QUESTION BEING ADDRESSED

Clinical trials of schizophrenia suffer from high rates of inconclusive results, in part due to imprecisions in endpoint measurements¹. Traditional paper-based clinical outcome assessments (COA) are not only characterized by high error rates, which have the potential to degrade signal detection, but they also require an additional step of manual data entry into electronic data capture (EDC) systems and source data verification monitoring, further adding to site burden and potential errors.

BACKGROUND

- The Positive and Negative Syndrome Scale² (PANSS), a widely used primary endpoint measure, is a complex scale with different scoring rules and conventions:
 - Scale has three major subscales (Positive, Negative, and General Psychopathology) that require raters to score 30 different items
 - Each item has a unique description, rating guidelines, scoring anchors and scoring conventions
 - Scoring involves use of an informant checklist, which helps in assessing patient symptoms
 - Raters are required to consult several sources during administration and scoring, a cumbersome process that can impede the interview and is prone to errors
- Collection of source data using a digital tablet device (eCOA) instead of paper forms has several advantages, including the elimination of calculation errors, flagging missing data, avoiding the need for source data verification, and reducing site burden associated with central oversight.
- The Virgil eCOA platform equips clinicians with tablet devices that provide built-in, real-time scoring and clinical guidance, and scoring consistency checks to help standardize measurements³.
- The present study investigated the extent to which the use of Virgil eCOA reduces errors in PANSS outcome measure in schizophrenia trials.

METHODS

- The first 288 paper-based administrations of the PANSS in two clinical trials of schizophrenia were compared against the first 288 Virgil eCOA administrations of the same scale in a separate schizophrenia trial. All studies were randomized, double-blind, multisite clinical trials.
- Discrepancies between rater and reviewer scores were identified via review of recordings and worksheets by the same cohort of blinded expert calibrated reviewers.
- The percentage of reviews with discrepancies of two or more points were compared between paper-based and eCOA administrations. The types of errors and rating quality metrics were also examined.

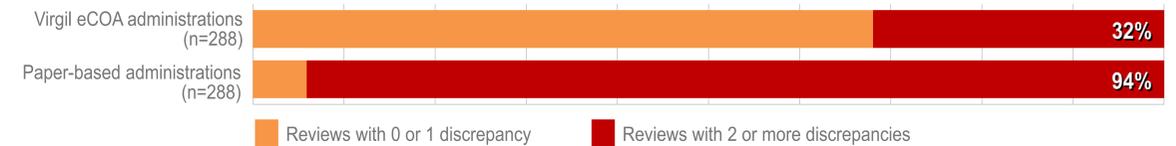
CONCLUSIONS

- Virgil eCOA administrations of the PANSS significantly reduced scoring errors as well as improved rating quality.
- Paper-based administration of the PANSS is prone to administration and scoring errors, which contribute to poor interrater reliability and inaccurate results.

RESULTS

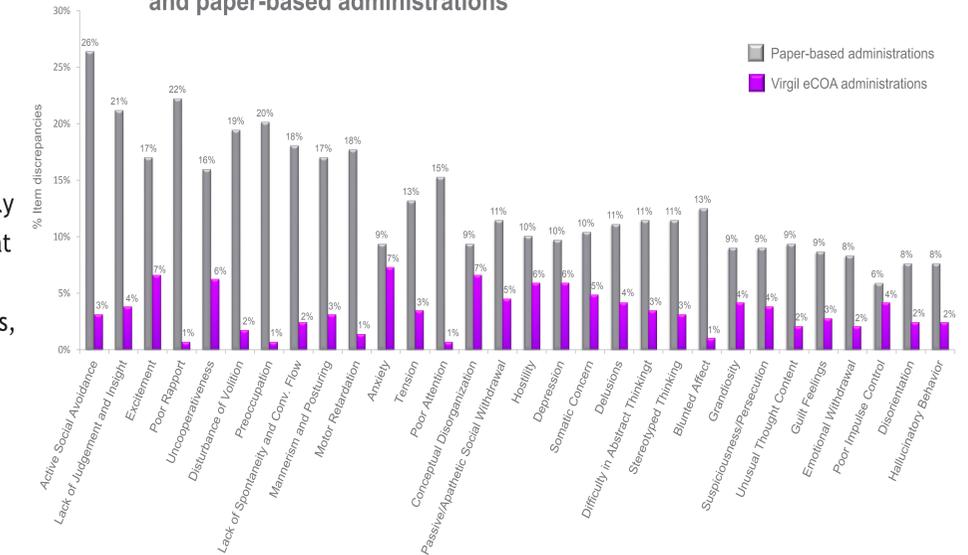
- Figure 1 compares the percentages of reviews with discrepancies in Virgil eCOA versus paper-based administrations. As the figure indicates, and ANOVA confirms, Virgil administrations showed significantly lower error rates compared to those administered on paper [F (1,576) = 88.4 p<.0001].

FIGURE 1. Percentages of reviews with discrepancies in eCOA administrations of the PANSS vs. paper-based



- Item level discrepancies are shown in Figure 2.
- Virgil eCOA administration reduced errors on all items compared to paper-based.
- Virgil eCOA also substantially reduced errors on items that showed high error rates in paper-based administrations, such as Active Social Avoidance and Lack of Judgement and Insight.

FIGURE 2. Percentages of PANSS item discrepancies in Virgil eCOA and paper-based administrations



- Virgil eCOA administrations showed a higher proportion of assessments that met rating quality criteria compared to paper-based administrations (Figure 3).

FIGURE 3. Percentages of Virgil eCOA and paper-based PANSS administrations meeting rating quality criteria



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