

## **eCOA Administration of the PANSS Minimizes Errors to Improve Signal Detection**

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### **The Methodological Question Being Addressed**

Traditional paper-based clinical outcome assessments (COA) are characterized by high error rates, which have the potential to degrade signal detection. They also require an additional step of manual data entry into electronic data capture (EDC) systems, as well as source data verification monitoring, further adding to site burden and the possibility of errors. The extent to which a new electronic COA (eCOA) platform reduces errors to improve data quality in schizophrenia trials was examined.

### **Background**

Clinical trials of schizophrenia suffer from high rate of inconclusive results, in part due to imprecisions in endpoint measurements. The Positive and Negative Syndrome Scale (PANSS), a widely used primary endpoint measure, is a complex scale with numerous scoring rules and conventions. Clinical outcome assessments with traditional paper-based administration, already recognized as cost- and time-inefficient, also contribute to human error, creating more variability in measurement. The Virgil eCOA platform provides clinicians with tablet devices in place of paper to collect source data with built-in real-time scoring and clinical guidance and scoring consistency checks to help standardize measurements. We investigated whether this electronic platform results in error reduction in PANSS outcome assessments in schizophrenia trials.

### **Methods**

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

### **Results**

The percentage of reviews with discrepancies was significantly lower in Virgil eCOA administrations compared to paper-based;  $F(1,773) = 519, p < .0001$ . Virgil administrations also substantially reduced errors on several items that showed high error rates in paper administrations (e.g., 26% scoring discrepancies on the Active Social Avoidance item in paper-based administration compared to 4% in Virgil). On rating quality metrics, Virgil administrations revealed a significantly higher proportion of

assessments that met quality criteria compared to those administered on paper;  $F(1,773) = 434$ ,  $p < .0001$ .

### **Conclusions**

Paper-based administrations of the PANSS are prone to scale administration and scoring errors that contribute to poor interrater reliability and inaccurate results. The Virgil eCOA platform not only has practical advantages, but can also reduce errors substantially while improving rating quality to increase the accuracy of signal detection.