

THE EVALUATION OF NEGATIVE SYMPTOMS BY VIDEOCONFERENCING IN A CLINICAL TRIAL

J.B.W. Williams^{1,2}, D. Popp¹, D.A. Osman¹, E.A. Cohen¹, M.J. Detke^{1,3}

¹MedAvante, Inc., Hamiton, NJ, ²Department of Psychiatry, Columbia University, New York, NY, ³Department of Psychiatry, Indiana University, Indianapolis, IN, USA

Introduction: Negative syndromes in Schizophrenia are of increasing interest to drug developers. Several assessment strategies have emerged for identifying negative symptoms including the NSA-16, PANSS negative symptom subscale and the Marder subscale. Assessment of patients with schizophrenia by videoconferencing has been shown to yield results equivalent to those obtained when the scale is administered face-to-face.

Objectives: To assess remote assessment of negative symptoms including blinding to protocol details and visit number, effectively eliminating enrollment and expectation biases.

Aims: To assess whether negative symptom scales can be reliably assessed in a clinical trial by videoconferencing.

Methods: The PANSS and the NSA-16 were administered to 227 subjects with schizophrenia in a randomized clinical trial via live videoconferencing by 17 blinded independent central raters. Subjects were interviewed at screen, at 11 more visits over 36 weeks, and at endpoint or 1 year. On a subset of subjects, a senior clinician observed and independently rated the PANSS and NSA as a quality control measure.

Results: ICCs between raters and observing trainers were .98 on the NSA total score (N = 65 pairs) and .96 on the PANSS total score (N = 69 pairs). ICCs of individual NSA items ranged from .72-1.0, with a mean ICC of .91. ICCs of PANSS subscales ranged from .94 - .96 with ICCs of .95 for the Marder subscale and .94 for the negative subscale.

Conclusion: Excellent item-level ICCs for the NSA suggest that negative symptoms can be rated reliably by videoconferencing using well-calibrated blinded independent raters.