Assessing the Severity of Anxiety Symptoms at Study Entry into Acute Schizophrenia Clinical Trials

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SUBMISSION DETAILS

What is the Methodological Question Being Addressed? The objective of this analysis was to preliminarily characterize the severity and stability of anxiety symptoms in a sample of subjects entering acute schizophrenia trials and to assess the impact on change from baseline to last visit for the PANSS total and other domains of schizophrenic symptoms.

Introduction Whereas, psychotic symptoms are relatively amenable to measurement, entry criteria for acuity, per se, in schizophrenia clinical trials can be challenging to operationalize, quantify and monitor for quality. Clinically, acute psychotic exacerbations are often associated with severe anxiety and tension. Anxiety and tension are not routinely formally included in the assessment of acuity, in clinical trials, however. In the current analysis we aimed to assess the severity, stability and impact on change from baseline of symptoms of anxiety and tension in patients entering acute schizophrenia trials.

Methods Screening and baseline data were pooled from 15 acute schizophrenia clinical trials. We assessed the screening and baseline severity of PANSS anxiety and tension items (G2 and G4), the proportion of subjects at study entry suffering from no anxiety (G2 score < 3), the magnitude of change in anxiety and tension between screening and baseline, and statistically compared the screening and baseline item severity (paired t-test), magnitude of change between screening and baseline (t-test) and presence of no anxiety symptoms in subjects with PANSS total below 100 with those scoring at least 100 at baseline (chi2 test). Additionally, in the blinded data we separately assessed the impact of change in anxiety and tension between screening and baseline on last visit change in PANSS total using regression analysis, correcting for baseline severity and study.

Results The dataset consisted from 4,667 screening and baseline paired PANSS assessments. There was no difference between screening and baseline anxiety severity (3.54(1.15) vs 3.55(1.15), p = ns) but there was a significantly higher tension severity at baseline (3.04(0.98) vs 3.11(0.98), p < 0.001). Unlike anxiety, tension significantly worsened by 0.07 points between screening and baseline. No anxiety was present in 16.16% of subjects at screening and 16.03% of subjects of baseline(NS), in subjects below 100 in 17.58% and in 13.46% in those scoring 100 or above at baseline (chi2 = 13.9, P < 0.001). Screening to baseline change in anxiety or tension resulted in a significant reduction of improvement at last visit in the blinded data (p <0.05).

Conclusion Our data indicate that subjects entering acute schizophrenia clinical trials enter predominantly with mild to moderate symptoms of anxiety and with mild tension. As well, over 16%

of subjects have no symptoms of anxiety, and even in the group of highly symptomatic subjects, no anxiety was seen in over 13% of subjects. Last visit PANSS improvement from baseline was significantly affected by instability in levels of of either of the anxiety or tension PANSS items during

screening. We further plan to assess the impact of screening to baseline changes in anxiety symptoms in unblinded data as these become available.

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Guidelines I have read and understand the Poster Guidelines

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Dr. Daniel and Dr. Kott have equity interests in Signant Health.

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