

Assessing PANSS change in screening period in acute schizophrenia clinical trials

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Methodological Issue Being Addressed To examine how individual PANSS items, subscales, and factors change during the screening phase of acute schizophrenia clinical trials.

Introduction Screening phases in acute schizophrenia trials often involve a wash-out of prior antipsychotic medication before randomization, which is expected to worsen symptoms. Yet, observed mean changes during screening are typically minimal. This retrospective analysis aimed to clarify the magnitude and pattern of changes at the PANSS item, PANSS subscale, PANSS factor and PANSS total score levels.

Methods Screening and baseline PANSS scores were pooled from 16 monotherapy trials including 6,422 participants with acute schizophrenia. For each subject, the change from screening to baseline was computed across 30 PANSS items, the three subscales, the five factors, and the total PANSS. Linear mixed-effects models were fitted for each variable, with change as the dependent variable, the screening score as a covariate, and random intercepts for protocol.

Results Significant changes were identified in 18 of 30 PANSS items: 15 worsened (mean change 0.027–0.10), most notably Somatic Concern (G1), while three improved (0.04–0.07), led by Active Social Avoidance (G16). The Negative subscale exhibited the greatest worsening, followed by General Psychopathology, whereas the Positive subscale remained stable. Among the factors, Disorganized Thought worsened most, followed by Negative and Positive factors, with Hostility/Excitement and Anxiety/Depression largely unchanged. Mean total PANSS increased by 0.67 points between screening and baseline.

Conclusion Despite medication wash-out, symptom changes during screening were small, with total PANSS worsening by less than one point. Approximately half of participants showed symptom worsening, while others remained stable or improved. Unexpectedly, negative symptoms exhibited the most consistent deterioration, a pattern that merits further study. We hypothesize that factors beyond medication discontinuation—such as setting or informant changes—may have contributed to this pattern.

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Keywords

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Guidelines I have read and understand the Poster Guidelines

Disclosures Alan Kott and Xingmei Wang are employees of Signant Health and hold stock/equity shares. David Daniel is an Executive Advisor to Signant Health. The authors declare no conflict of interest.