

Association Between SCID Screening Questions Flags and Screen Failure Outcomes in Major Depressive Disorder Trials

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What is the Methodological Issue Being Addressed? Clinical trial screening for major depressive disorder (MDD) relies heavily on structured diagnostic interviews and symptom severity scales, which may not fully capture contextual or exclusionary clinical features relevant to eligibility. The SCID Screening Questions (SSQ) are a brief adjunctive tool to identify diagnostic inconsistencies, comorbidities, and protocol-specific exclusion criteria early in screening. However, their utility as an independent screening instrument when administered by independent raters has not been systematically evaluated.

This study examines whether the SSQ can serve as a reliable, informative adjunct to traditional screening methods in large, multi-site clinical trials. We evaluated the frequency, type, and distribution of SSQ flags and their relationship to screen failure outcomes, including MADRS-based and non-MADRS-based exclusions.

Introduction The SSQ is a modifiable, short screening tool used to assess DSM disorders and inclusion/exclusion criteria, with items derived from the SCID for the DSM. It is intended as an independent assessment of diagnostic inclusion/exclusion criteria and overall appropriateness for trial participation (e.g., cognitive impairment), used in addition to a site-based diagnostic interview.

The SSQ generates “flags” that prompt re-evaluation of a subject’s suitability for the trial. We evaluated the usefulness of the SSQ, administered by independent raters at the screening visit, to identify participants who may meet protocol-exclusionary diagnostic criteria leading to screen failure, as well as the type, frequency, and number of SSQ flags and their relation to inclusion/exclusion outcomes.

Methods We analyzed data from three global, multi-site Phase III MDD trials that included the SSQ (N = 1,802). Logistic regressions examined associations between number and type of SSQ flags and screen failure. Of 1,802 subjects, 925 (51.3%) were enrolled and 877 (48.7%) failed screening; 211 screen failures were due to MADRS criteria and 666 to non-MADRS reasons.

Results Across the cohort, 1,550 SSQ flags were triggered. Subjects who failed screening had more SSQ flags than enrolled subjects (1.17 ± 1.75 vs. 0.57 ± 1.10); this difference remained when subjects who failed solely on MADRS criteria were excluded (1.21 ± 1.90 vs. 0.57 ± 1.10).

Logistic regression showed that the total number of SSQ flags was significantly associated with

increased likelihood of screen failure (estimate = 0.3255, $p < .001$), and this association remained when MADRS-based exclusions were removed (estimate = 0.3089, $p < .001$).

Item-level analyses identified several SSQ domains associated with higher screen failure risk, including MDD diagnostic reconsideration (estimate = 1.704), duration of MDD (0.51–0.57), PTSD (0.72–0.79), and panic disorder (0.72–0.73). The most frequent SSQ flags involved duration of MDD, PTSD, and MDD diagnostic reconsideration, suggesting that diagnostic clarification and comorbidity assessment are key drivers of screening outcomes.

Conclusion In summary, SSQ-derived flags are common in MDD trial screening and provide information beyond site-based diagnostic assessments and symptom scales. Both total and item-level flags were strongly associated with screen failure, including non-MADRS exclusions, indicating that the SSQ captures clinically relevant exclusion factors not reflected in severity thresholds. These findings support the SSQ as a complementary tool to improve early identification of ineligible participants and enhance screening efficiency in MDD trials.

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Guidelines I have read and understand the Poster Guidelines

Disclosures The authors are all full-time employees of Clario, a Thermo Fisher Scientific company, and report no conflicts of interest for this work.

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