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FEASIBILITY OF CENTRALIZED RATINGS FOR MENTAL HEALTH SAFETY SCREENING IN A NON-PSYCHIATRIC CLINICAL TRIAL

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Introduction: Centralized ratings by telephone have proven feasible for assessment of psychiatric diagnosis, symptom severity, and suicidality, and may be used for safety assessments in non-psychiatric trials with sites that do not employ staff experienced in psychiatric assessment.
Objective: To assess whether centralizing assessments with mental health experts enables immediate clinical follow-up and actionable diagnostic support for investigators.
Aims: To examine the feasibility of centralized ratings in a Phase III dermatology clinical trial for safety assessments.
Methods: 1127 subjects enrolled in a trial of medication for their dermatologic condition were assessed via telephone by central raters who administered the SCID-CT, C-SSRS and PHQ-8 at screening. At monthly visits, central raters performed the C-SSRS, PHQ-8, GAD-7 and items designed to detect emergent psychotic symptoms.
Results:
Screening: 34 subjects were excluded on the basis of SCID-CT diagnosis. Based on diagnosis or severity, subjects were classified as being in no need of mental health services, having mild psychiatric symptoms (referred to local mental health service provider; n=33), moderate (immediate referral for psychiatric evaluation; n=17), or severe (immediate escort to emergency room; n=0).
One subject reported suicidal ideation on the C-SSRS, 10 reported self-injurious behavior, and 5 reported suicidal behavior in the last year.
Follow-Up: No subjects reported suicidal ideation or behavior at any of the 6861 follow-up assessments. One subject reported self-injurious behavior and two reported emergent psychotic symptoms.
Conclusions: This study established the feasibility and acceptability of routine screening and monitoring of psychopathology and suicidality by central raters in a non-psychiatric population.

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