External Review of Videotaped Diagnostic and Rating Interviews in Global Schizophrenia Clinical Trials: Initial Findings

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BACKGROUND

There is increased concern with signal detection capability in global schizophrenia clinical trial settings. (1) External review of site ratings and diagnostic proceedings with rapid feedback to the site and sponsor has been proposed as a means of maintaining quality and reliability of clinical trial assessments in this context.

METHOD

Prior to study initiation, raters were trained at investigators meetings and, in some cases interview and rating of live actors was required. External reviewers were trained to portray schizophrenic symptoms. A proprietary video/audio recording system (VERIFIED) is being utilized to assess diagnostic and scoring accuracy and interview quality. External reviewers provide feedback to sites and sponsors is feasible in schizophrenia clinical trials settings. Interview quality at the sites and agreement between site and external PANSS ratings was relatively high.

RESULTS

SUMMARY OF RESULTS I:

In the available data, exact matches were obtained between the site and external rater on 60% or more of ratings for all 30 PANSS items.

SUMMARY OF RESULTS II:

155 videotaped PANSS administrations at sites were graded for interview quality by external reviewers using the RISA. 74.7% were regarded as excellent (RISA Score 28-30), 20.7% as acceptable (RISA score 24-27) and 4.6% as poor or unacceptable.

SUMMARY OF RESULTS III:

In the available data, mismatches between the site and external raters of 2 anchor points or greater in scoring any PANSS item were relatively uncommon and only exceeded 10% of ratings on items P2 (Conceptual Disorganization) and N7 (Stereotyped Thinking).

SUMMARY OF RESULTS IV:

In the available data, mismatches between the site and external raters of 2 anchor points or greater in scoring any PANSS item were relatively uncommon and only exceeded 10% of ratings on items P2 (Conceptual Disorganization) and N7 (Stereotyped Thinking).

OBJECTIVES OF VIDEO/AUDIO SURVEILLANCE

- Improve data quality by ensuring that diagnostic and symptom severity measurements are reproducible to an objective external reviewer
- Accurate, thorough, therapeutically neutral interview
- Scoring based on adequate information
- Scoring reflects proper use of measurement or diagnostic tool
- Provide continuous "surveillance effect" (monitoring, feedback, refinement and retraining) throughout the study

REFERENCES


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