Rater Training on SANS and Monitoring of Rater Performance during Clinical Trials

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Abstract

Training a heterogeneous group of raters on the Scale for the Assessment of Negative Symptoms (SANS) is challenging as negative symptoms of schizophrenia are very difficult to measure. This study evaluates ratings on the SANS and presents a novel methodology, Signal Enhancement System (SES), used in monitoring rater performance during the trial.

Introduction

• Training was provided on Scale for the Assessment of Negative Symptoms (SANS, 25 items version) to investigators participating in multinational randomised controlled clinical trials.

• The SANS is challenging because negative symptoms are poorly understood and difficult to measure as they involve the absence of a symptom rather than the presence of one. Moreover, there is no standardized structured interview used in the administration of the SANS.

• We evaluated ratings using the SANS in a rater training program and present a novel methodology, Signal Enhancement System (SES), used in monitoring rater performance during the trial.

Methods

• 80 raters from 8 countries and 2 sites participated in a SANS rater training program through online and face-to-face training at the New York University School of Medicine, New York, NY, USA, and Schering-Plough, Oss, Noord Brabant, Netherlands.

• A structured SANS interview was developed by the expert trainer and training provided to raters, raters had to be certified before being allowed to rate in the study.

• The training program incorporated both online training via the web followed by live training at the Investigator Meeting (IM).

• A structured SANS interview was developed by the expert trainer and training provided to raters, raters had to be certified before being allowed to rate in the study.

Results of SES

• SANS baseline and endpoint comparison showed expectancy bias in clinical improvements (Figure 5).

• Inter-rater agreement was calculated using kappas coefficient, highest kappas level was observed in the certification session I (Kappa = 0.89, p < 0.01) substantial agreement, and lowest in certification session III (Kappa = 0.56, p < 0.01 poor agreement).

• Difficult to rate items – raters who failed the certification session had difficulty rating alogia which included poverty of speech, poverty of content of speech, blocking and increased latency of responses.

• Inter-rater reliability

- There is concordance in overall improvement of subjective after site raters and independent raters (Figure 6).

- Despite the challenge of negative symptoms assessment, the results indicate that with an intensive training program and in-vivo monitoring (live on-screen effect), sufficient inter-rater reliability can be attained.

Conclusions

• Negative symptoms are a challenge to assess adequately with single being most difficult to rate.

• Training alone does not ensure reliable ratings and statistical analysis of ratings from the site cannot establish whether the patient interview was successful or not. Signal Enhancement System was developed to monitor patient interviews and ratings throughout the clinical trials.

• SES was well accepted by the ethics committees, patient, SIs, RIs and COrA.

• It was used in 6 countries and in European countries which had rudimentary internet access, at Sites using only 1.2% had technical problem leading to data loss. The technology is highly secure maintaining patient confidentiality.

• SES is an effective tool to control for bias, interview quality, inter- and intra-rater reliability (signal enhancement).

• The SANS methodology with video recordings and second opinion ratings provides a new tool in the refinement and validation of rater scores, the principle ‘‘instructor knows what patients feel’’

• Adequate and appropriate training and monitoring using SES during the study leads to improved SRs performance.

References


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Figure 1: The Training and Certification Process

Figure 2: Signal Enhancement System (SES) process flow chart

Figure 3: Signal Enhancement System (SES) Portal

Table 1: Pass and fail percentage of raters in certification session I, II & III

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<th>Fail (%)</th>
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