As drug-placebo differences have diminished over time in global schizophrenia clinical trials, the quality of interviews and ratings performed by sites has come under increasing scrutiny. The Ratings Quality Questionnaire (RQQ) is a culturally neutral global impression-like two item tool for evaluation of the quality of data collected by sites and diagnostic procedures. The RQA is a 16 item scale with 4 domains, providing a comprehensive assessment of interview quality. We describe the development of the current version, which is the RQA in evaluation of interview and ratings quality in ten global or international schizophrenia clinical trials.

### Table 1: Rater Quality Questionnaire

<table>
<thead>
<tr>
<th>Domain</th>
<th>Anchor Points</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. The patient’s interview/reason required to complete the interview is clearly documented.</td>
<td>1. No deficiencies</td>
</tr>
<tr>
<td>2. The patient’s interview material is required to complete the interview is clearly documented.</td>
<td>1. No deficiencies</td>
</tr>
</tbody>
</table>

### METHODS

Many of the studies comprising the pooled dataset are ongoing. Thus, the number of interviews evaluated with the RQQ has grown from 906 at the time the ECNP abstract was submitted to 1187 as of August 2012. The description of the RQA has been updated accordingly.

A proprietary video/audio recording system was utilized to record PANSS rating procedures in ten global or international schizophrenia clinical trials conducted in North America, Europe, South America and Asia. Digitized video/audio recordings were collected from 10 randomized clinical trials from 100 sites across 75 countries. The PANSS rating procedure was recorded using a video/audio recording system in ten global or international schizophrenia clinical trials. Sites were trained by interactive procedures uniform in quality of interview and rating procedures performed by sites have come under increasing scrutiny (1). The Ratings Quality Questionnaire (RQQ) is a culturally neutral global impression-like two item tool for evaluation of the quality of data collected by sites and diagnostic procedures. The RQA is a 16 item scale with 4 domains, providing a comprehensive assessment of interview quality. We describe the development of the current version, which is the RQA in evaluation of interview and ratings quality in ten global or international schizophrenia clinical trials.

### RESULTS

**SUMMARY OF RESULTS I:** For the RQA analysis, the current pooled dataset consists of 1187 evaluated interviews. The mean RQA scores for sufficiency of the data collected by interview and competency in use of the rating scales were 1.35±.51 and 3.13±.30, respectively.

**SUMMARY OF RESULTS II:** In 63.2% (n=769) of visits the patient and/or informant material required to rate the patient was considered as fully proficient and sufficient, 33.3% (n=398) as some deficiencies but overall adequate, and 1.5% (n=22) as inadequate to rate the patient.

**SUMMARY OF RESULTS III:** What is the overall quality of the patient and/or informant material collected for this subject visit?

| Quality | Total
<table>
<thead>
<tr>
<th></th>
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</tr>
</thead>
<tbody>
<tr>
<td>Excellent</td>
<td>123</td>
</tr>
<tr>
<td>Acceptable</td>
<td>799</td>
</tr>
<tr>
<td>Poor or Unacceptable</td>
<td>144</td>
</tr>
</tbody>
</table>

**SUMMARY OF RESULTS IV:** For the RQA analysis, the current pooled dataset consists of 1187 evaluated interviews. The mean RQA scores for sufficiency of the data collected by interview and competency in use of the rating scales were 1.35±.51 and 3.13±.30, respectively.

**SUMMARY OF RESULTS V:** 1442 videotaped PANSS administrations at sites were graded for interview quality using proper technique. 19.5% of interviews had minor deficiencies in both information gathering and scoring. 10.8% of interviews had minor deficiencies in information gathering but the information was scored using proper technique. 10.5% of interviews had minor deficiencies in both information gathering and scoring.

### DISCUSSION

The initial data indicate that in global clinical trial settings interviews and ratings are well done, the feedback to investigators the quality of interview and ratings. It is essential to develop tools like RQA and RISSA were judged to be adequate or better by external reviewers in the larger majority of cases. We speculate that rapid feedback to the raters from the external reviewers may be useful in maintaining interview and ratings quality in the current studies. These results are preliminary and additional data will be reported from ongoing studies.

Future presentations will address rater demographic, clinical and environmental variables associated with interview and ratings quality. In addition, the psychometric qualities of the RQA, including internal reliability, test-retest reliability, content validity and convergent validity will be addressed.

### REFERENCES

