Discrepancies between the PANSS and CGI-S scores at baseline are a marker for subsequent data quality issues in schizophrenia clinical trials

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BACKGROUND

■ Data quality concerns are frequent in schizophrenia subjective outcome datasets, often with detrimental impact on signal detection
■ Our previous research indicates post-baseline data quality concerns are often significantly associated with the presence of similar data quality concerns in the screening period identified between screening and baseline visits (Kott & Daniel, 2016)
■ In the current analysis we report the predictive value of a single data quality marker at baseline, discrepancies between the CGI-S and PANSS score

RESULTS

■ The percent of post-baseline visits affected by the examined data quality issues in the dataset is summarized in figure 1
■ The odds of identifying a particular data quality issue were significantly increased for all examined issues except PANSS logical inconsistencies in subjects who had a PANSS vs. CGI-S discrepancy (figure 2)

Table 1: List of examined post-baseline data quality issues

<table>
<thead>
<tr>
<th>Data quality issue</th>
<th>Label on graphs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Identical scoring of 30/30 PANSS items across consecutive visits</td>
<td>Identical PANSS</td>
</tr>
<tr>
<td>Unusually large change in the PANSS</td>
<td>Large Change</td>
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<tr>
<td>Erratic changes in the PANSS</td>
<td>Erratic Rating</td>
</tr>
<tr>
<td>Logical within PANSS-items discrepancy</td>
<td>PANSS Logical Inconsistency</td>
</tr>
<tr>
<td>Discrepancies between CGI-I scores and changes in PANSS from baseline</td>
<td>CGI-S vs. CGI-I Discrepancy</td>
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<tr>
<td>Discrepancies between CGI-I scores and changes in PANSS from baseline</td>
<td>PANSS vs. CGI-I Discrepancy</td>
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Figure 2: Effect of presence of PANSS vs. CGI-S discrepancy at baseline on the odds of post-baseline data quality concerns

■ Similarly, the incidence rates of post-baseline data quality issues were significantly increased for the discordant subjects with the exception of PANSS logical discrepancies (figure 3)

Figure 3: Effect of presence of PANSS vs. CGI-S discrepancy at baseline on the incidence of post-baseline data quality concerns

CONCLUSIONS

■ The current analysis expands on the previously reported significant association between the presence of post-baseline data quality concerns with the presence of the same data quality concerns before baseline
■ The data show that a baseline discrepancy between the PANSS total score and CGI-S score is associated with various data quality concerns further down the study after randomization
■ The fact that post-baseline data quality concerns are associated with findings of data quality concerns in the screening period allows early identification and prevention of future potentially problematic ratings
■ This can be achieved by pairing data analytics with other data quality methods, such as intelligent eCOAs, audio/video recordings, computer simulated scores, etc.
■ The findings of this analysis are preliminary and await replication

REFERENCES