Identical Ratings Are An Early Marker of Data Quality Issues

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METHODOLOGICAL QUESTION

- Whether there is an association between the presence of identical PANSS ratings between screening and baseline and the presence of identical PANSS ratings after randomization.

INTRODUCTION

- Early identification of issues that may decrease signal detection is the primary focus of data quality monitoring in clinical trials
- We have previously identified identical PANSS ratings (30/30 PANSS items scored the same across consecutive visits) as markers of poor ratings quality (Daniel and Kott, 2014)
- In the current analysis, we examined whether the presence of identical PANSS ratings between the screening and baseline visits predicted identical ratings after randomization

METHODS

- We analyzed data from 4,761 randomized subjects into 10 global schizophrenia clinical trials who had PANSS data available for screening, baseline and at least one post-baseline visit
- We assessed the association between the presence of identical ratings between the screening and baseline visits and the presence of identical ratings at post-baseline visits utilizing the Chi-square statistic and by calculating the odds ratios
- Analyses were applied to the combined data set as well as individual clinical trials

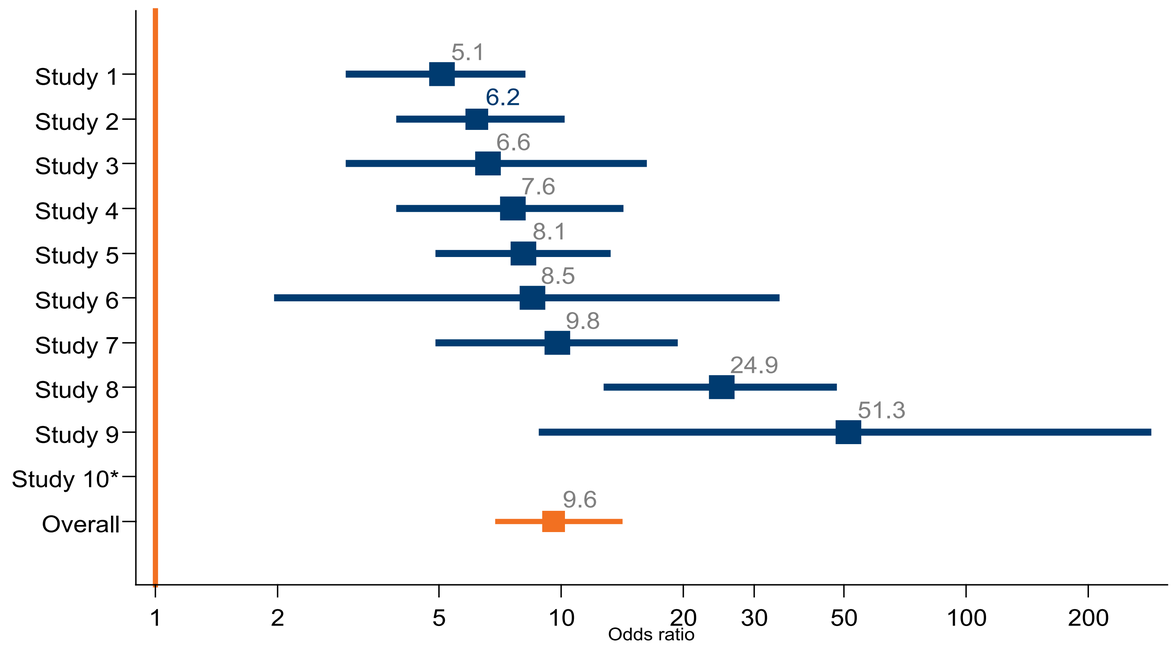
RESULTS

- Out of the 4,761 randomized subjects, 440 (9.24%) had their baseline PANSS scores identical to screening scores
- 762 (15.99%) subjects had at least 1 pair of identical ratings that included a post-baseline visit
- Out of these 762 subjects, 248 (32.55%) had their baseline PANSS scores identical to screening scores
- The association between the presence of identical rating at baseline and post-baseline visit was found to be significant for the whole dataset and for each study individually (table 1; figure 1)

Table 1: Individual Studies' Details

Study	N randomized	Identical at baseline N (%)	Identical at at least one post baseline visit N (%)	Identical at baseline and at least one post-baseline visit N (%)	Chi2	p	Odds ratio	Confidence interval
Study 1	609	75 (12.32%)	133 (21.84%)	39 (6.40%)	45.58	<0.001	5.07	3.06 - 8.40
Study 2	608	78 (12.83%)	131 (21.55%)	43 (7.07%)	59.70	<0.001	6.17	3.73 – 10.17
Study 3	376	23 (6.12%)	47 (12.50%)	10 (2.66%)	21.50	<0.001	6.57	2.69 – 16.03
Study 4	573	56 (9.77%)	93 (16.23%)	29 (5.06%)	57.71	<0.001	7.60	4.23 – 13.66
Study 5	608	85 (13.98%)	137 (22.53%)	52 (8.55%)	84.54	<0.001	8.12	4.95 – 13.31
Study 6	323	9 (2.79%)	31 (9.60%)	4 (1.24%)	12.96	<0.001	8.50	2.16 – 33.56
Study 7	581	48 (8.26%)	78 (13.43%)	25 (4.30)	67.27	<0.001	9.84	5.22 – 18.55
Study 8	580	56 (9.66)	79 (13.72%)	38 (6.55)	154.97	<0.001	24.87	13.05 – 47.41
Study 9	459	7 (1.53%)	26 (5.66)	5 (1.09%)	57.53	<0.001	51.31	9.40 – 280.11
Study 10	44	3 (6.82%)	7 (15.91%)	3 (6.82%)	17.02	<0.001	-	-
Overall	4,761	440 (9.24 %)	762 (15.99%)	248 (5.21%)	587.95	<0.001	9.57	6.56 - 13.95

Figure 1: Odds ratio of having an identical rating in the post-baseline visit for those subjects who had identical rating at baseline vs. those who had not



* Study 10 odds ratio could not be calculated as all subjects with ratings identical at baseline had at least one post-baseline visit identical in this small study

CONCLUSIONS

- Our analyses found that the presence of PANSS identical ratings between screening and baseline robustly predicted identical ratings for that subject after randomization
- This represents an important opportunity to identify and address data quality issues prior to randomization
- The presence of identical ratings at baseline represents a highly concerning finding
  - » It suggests that there will likely be more identical ratings recorded for the subject later in the study
  - » It likely modifies the subjects' baseline severity, thus distorting the assessment of change from baseline to endpoint
- To assure quality of screening and baseline evaluations and appropriate subject selection available options for external review such as audio/video recordings of site assessments, site completed electronic PANSS and subject validation workbooks and independent telephone assessment of the subject should be used

REFERENCES

1. Daniel, D.G. & Kott, A. (2014) Is identical scoring of the PANSS across consecutive visits a marker of poor data quality? Presented as a poster at the International Society of Clinical Trials Methodology (ISCTM) Autumn Conference, October 6 – 8, 2014, Boston, MA USA.

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