Rating Patterns Identified During Screening Predict Subsequent Rating Issues
Daniel, David 1; Lee, Jennifer 2; Forbes, Andy 2; Pfister, Stephanie 2; Wang, Xingmei 1; Ouyang, John 2; Kott, Alan 1
1 Bracket Global, LLC 2 Otsuka Pharmaceutical Development & Commercialization, Inc.

METHODOLOGICAL QUESTION
Can analysis of patterns of symptom measurement during the screening phase identify erroneous raters?

INTRODUCTION
Blinded data analytics are a non-intrusive method of reviewing blinded clinical trial ratings aiming to identify rating patterns associated with increased non-specific variance, errors in rating techniques, placebo response and poor signal detection. In a post-hoc investigation we assessed whether discrepancies at the baseline visit between scales used for entry and efficacy, respectively, were predictive of errors in scoring after randomization.

METHODS
Available baseline data from 1310 subjects were used to predict the PANSS scores given the BPRS ratings. As a PANSS discrepant subject we identified those subjects where the actual PANSS score differed from the predicted by more than 2 standard deviations. Using logistic and binomial regression we then estimated the odds ratio (OR) and the incidence rate ratio (IRR) of the following post-baseline data deviations. Using logistic and binomial regression we then estimated the odds ratio (OR) and the incidence rate ratio (IRR) of the following post-baseline data deviations.

RESULTS
As shown in Figure 1 and Figure 2 the presence of baseline discrepancies between the BPRS and the PANSS scores significantly increased the odds and the incidence rate of the post-baseline large (OR = 1.95[1.15-3.21]; IRR = 2.39[1.55-3.69]) and erratic (OR = 4.58[2.03-10.34]; IRR = 4.33[1.69-11.07]) PANSS changes and of the discrepancies between the CGI-I score and change in CGI-S from baseline and CGI-I score; e) discrepancies between the change in PANSS from prior visit; d) erratic changes in PANSS; e) discrepancies between the change in CGI-S from baseline and CGI-I score; f) discrepancies between the change in PANSS from baseline and CGI-I score comparing the group of PANSS discrepant subjects with those, who were not discrepant at baseline.

CONCLUSIONS
In the current analysis we found that at the baseline visit discrepancies between a conceptually related inclusion and efficacy instrument were predictive of numerous rating errors after randomization. We have previously reported that other rating errors during the screening period are predictive of post-randomization rating errors.

REFERENCES
3. Kott, Alan; Lee, Jennifer; Forbes, Andy; Pfister, Stephanie; Ouyang, John; Wang, Xingmei; Daniel, David (2016): Logical Inconsistencies among PANSS items are associated with greater placebo response in acute schizophrenia trials – A post-hoc analysis. Poster presentation at the 2016 International Society for CNS Clinical Trials and Methodology (ISCTM) Fall Conference, 26-27 September, Philadelphia, PA, USA.

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