

## P02-135 - A PATTERN RECOGNITION MATRIX FOR PLACEBO-RESPONSE IN SCHIZOPHRENIA

**M. Opler**

*ProPhase LLC, New York, NY, USA*

**Objectives:** There is a need for real-time capability to detect inconsistencies in efficacy outcome measures and to predict individual-level or group-level placebo response. Training and calibration to improve reliability is one method; though this can be undermined by the enrollment of placebo responders.

**Methods:** A pattern recognition matrix for placebo-response in schizophrenia was developed based on a Phase II study of schizophrenia conducted in the US. A data monitoring algorithm based on the Positive and Negative Syndrome Scale (PANSS) was retrospectively applied to the unblinded data and score patterns for the placebo responders versus placebo non-responders were analyzed.

**Results:** A total of 35 placebo responders and 35 randomly selected placebo non-responders were compared. For specific patterns during the first 2 visits, patients were significantly likely to be placebo responders. Within this sample of patients who were randomized to placebo, those who demonstrated the pattern within the initial study visits were approximately three times more likely (OR=2.9, p=0.027) to demonstrate a placebo response.

**Conclusion:** This initial finding suggests that this method could aid in the detection of placebo response early in a trial. In concert with a data-monitoring process we would expect more robust signal detection. The use of the same system, coupled with ongoing training has demonstrated significant improvements in reliability, increasing the ICC by 19% in a 3-month period. If deployed at startup, this method provides a cost-effective way of managing the data quality in RCTs.