Identifying Sites of Concern in PD Studies – A Risk Based Approach

Alan Kott, MUDr1 and Jina Swartz, MD, PhD2
1Bracket, Prague, Czech Republic, 2Bracket, Reading, UK

BACKGROUND

- Failed clinical trials represent a serious problem in CNS research, including Parkinson’s disease (PD).
- While there have been many reasons identified as contributing to clinical trial failures, measurement error represents an important contributor that can be minimized through careful data scrutiny and remedial action.
- We present a targeted methodology promoting risk based monitoring of individual sites that allows near real time tracking, remediation and, if necessary, recruitment limitation at identified sites of concern.

METHODS

We assessed the quality of individual sites using the following clinically defined risk criteria:

1. Clustering of subjects around UPDRS part III inclusion criteria at screening and/or randomization;
2. Proportion of visits with a Change in Lateral Predominance (Kott, Swartz, Xu; 2012);
3. Proportion of Identical visits (Kott, Swartz, 2013); and
4. Proportion of Erratic Ratings.

RESULTS

- Our dataset consisted of more than 11,118 evaluable subject visits across 161 sites.
- 44 (27%) sites were identified as potentially concerning based on their overall quality score reaching statistical significance after applying Bonferroni correction.

CONCLUSION

- We present an example of utilization of a methodology allowing identification of sites of concern using well-defined clinical risk criteria.
- Categorizing sites by recruitment and overall quality score allows a targeted review of the most at-risk sites. The detailed analysis of individual risk criteria allows the development of a tailored, actionable plan to address the findings at the site in question.
- While the current analysis represents a retrospective analysis of all available data, similar approaches can be applied to near real time site reviews promoting a risk-based approach to monitoring of individual sites.

REFERENCES

Kott A, Swartz J, Xu Y. Changes in laterality predominance – a means of identifying sites of concern in PD clinical trials. Poster presented at the 16th International Conference on Alzheimer’s Disease and Parkinson’s Disease - ADPD Meeting, 6-10 March 2013, Florence, Italy.

This poster is financially supported by Bracket.