Identical Item Scores Across Visits in CNS Trials with Focus on Parkinson’s Disease. Mapping the Territory.

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METHODS
■ An “Identical visit” was defined as any visit that shares the same item score set as the visit immediately preceding it
■ We analyzed available clinical data from multiple sponsor trials, across three CNS indications, for the presence of such “identical visits”
■ Pooled data results as well as results from only the subset of data representing Parkinson’s disease (PD) trials with initial analyses are presented

RESULT I
■ The dataset consisted of 101 863 subject visits across three indications:
  » Major depressive disorder (N=54 011)
  » Schizophrenia (N=36 734)
  » Parkinson’s disease (N=11 118)
■ 85 087 subject visits had the potential to be identified as an “Identical visit”
■ In the entire dataset, 5,434 (6.4%) of “Identical Visits” were identified
■ There were significant differences identified in “Identical Visits” distribution across visits (χ² = 77.4; df = 4; p < 0.05) (Figure 1)

RESULT II
■ In the PD dataset overall 1 652 (16.8%) “Identical Visits” were identified
■ The mean proportion of “Identical Visits” at a site was 14.3% while the median was only 4.2%, indicating a highly skewed distribution of “Identical Visits” across sites (Figure 2)
■ There were significant differences identified in “Identical Visits” distribution across visits (χ² = 77.4; df = 4; p < 0.05) (Figure 3)
■ No significant correlations were identified between the size of the site and the mean UPDRS score at randomization and the proportion of “Identical Visits” at a site (Figures 4 and 5)

CONCLUSION
■ We suggest that the identification of “Identical Visits” at a site be used as a risk factor in risk-based monitoring
■ Sites with a large proportion of “Identical Visits” should be carefully monitored to assess the reasons underlying the observed discrepancies and remedial action employed, where necessary
■ Further research is warranted

REFERENCES