The utility of enhanced data surveillance on the presence of data quality concerns in acute schizophrenia clinical trials. A post hoc analysis

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SUBMISSION DETAILS

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Methodological Issue Being Addressed In CNS clinical trials do data quality assurance procedures have a measurable impact on data quality?

Introduction To address increasing placebo response and diminishing separation between drug and placebo in CNS clinical trials the industry has increasingly adopted enhanced methods of data quality assurance. Beyond traditional rater training these methods include but are not limited to automated edit checks of data on eCOA platforms, audio and video recording of subject interviews at the site with independent review and scoring, sophisticated analytical solutions on individual and aggregate data and rapid remediation of identified issues. In the current post-hoc analysis we compared measures of data quality in acute schizophrenia trials that did not include any of these measures with trials that did.

Methods Data were extracted from 4 trials that had no enhanced data quality assurance implemented and 5 trials that implemented intelligent eCOA, audio reviews and analytical data quality methods. Despite differences in details, the design and intended study populations were roughly comparable between the two sets of trials. We assessed 3 putative markers of data quality, namely inclusion clustering (baseline scores within 5 points from lower inclusionary cut-off), identical PANSS ratings – 30/30 PANSS items rated exactly the same at consecutive visits and within PANSS logical errors. We compared the presence of these markers individually and in aggregate using chi2 tests between the two types of trials.

Results The dataset consisted of a total of 24,080 visits from a total of 3,229 subjects. Inclusion clustering was recorded in 202/1,606 (12.6%) of subjects in trials without and 103/1,623(6.4%) of subjects in trials with enhanced data quality methods, $chi2(1) = 36.6$, $p < 0.001$. Identical ratings were recorded in 470/10,793(4.4%) instances in trials without and 28/9,485(0.3%) instances in trials with enhanced data quality methods, $chi2(1) = 347$, $p < 0.001$. PANSS logical errors affected 622/12,401(5.0%) PANSS assessments in trials without and 301/11,679(2.6%) assessments in trials with enhanced data quality methods, $chi2(1) = 97$, $p < 0.001$. Finally, at least one of the 3 errors affected a total of 1,249/12,401(10.1) visits in the trials without and 429/11,679(3.7%) visits in the trials with enhanced data quality methods, $chi2(1) = 380$, $p < 0.001$.

Conclusion In this post-hoc analysis of trials comparable in design in schizophrenia, enhanced data quality assurance methods significantly reduced the presence of clinically meaningful data quality concerns. Overall, the amount of errors decreased by 63% but was most pronounced in identical ratings where the implementation of enhanced data quality assurance methods reduced

their presence by 93%. Among the limitations of interpretation of our analyses are the post-hoc rather than prospective nature of the design and differences we could not control for, e.g. time when study was conducted, countries in which the trials were conducted, etc. Despite these limitations, the strength of the findings is consistent with benefits of measures taken by the industry to improve data quality.

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Guidelines I have read and understand the Poster Guidelines

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