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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INTRODUCTION

- To address increasing placebo response and the number of failed clinical trials in CNS, industry sponsored clinical trials often utilize 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 site interviews with independent review and scoring, sophisticated analytical solutions on individual and aggregate data and rapid remediation in case of identified issues.
- In the current post-hoc analysis we compared data quality in acute schizophrenia trials that did not include any of these measures with trials that did.

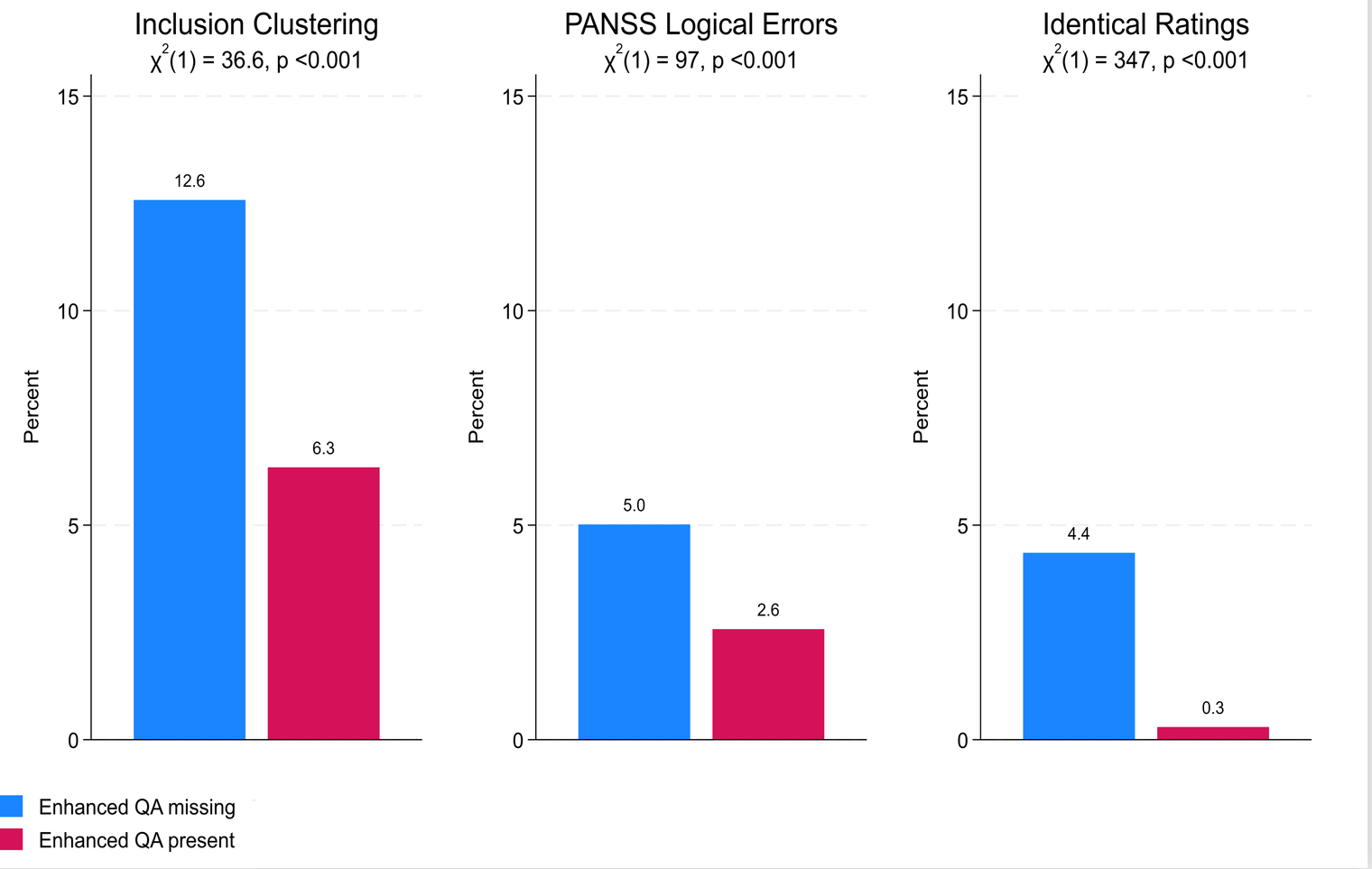
METHODS

- 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 comparable between the trials.
- We assessed 3 markers of data quality, namely:
  1. Inclusion clustering (baseline scores within 5 points from lower inclusionary cut-off)
  2. Identical PANSS ratings – 30/30 PANSS items rated exactly the same at consecutive visits
  3. 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(6.3%) of subjects in trials with enhanced data quality methods, chi2(1) = 36.6, p <0.001. (Figure 1)
- 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. (Figure 1)
- 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. (Figure 1)
- 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.

FIGURE 1: DATA QUALITY IN STUDIES WITH AND WITHOUT ENHANCED DATA QUALITY MONITORING METHODS



DISCUSSION

- 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%.
- The limitations of our analyses stem from the post-hoc rather than prospective nature of the design and could be affected by a number of factors 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 are consistent with benefits of the enhanced measures frequently utilized in industry sponsored clinical trials to support the quality of collected data.

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