Is Rapid Recruitment in Acute Schizophrenia Trials Associated with Increased Data Quality Concerns?

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INTRODUCTION

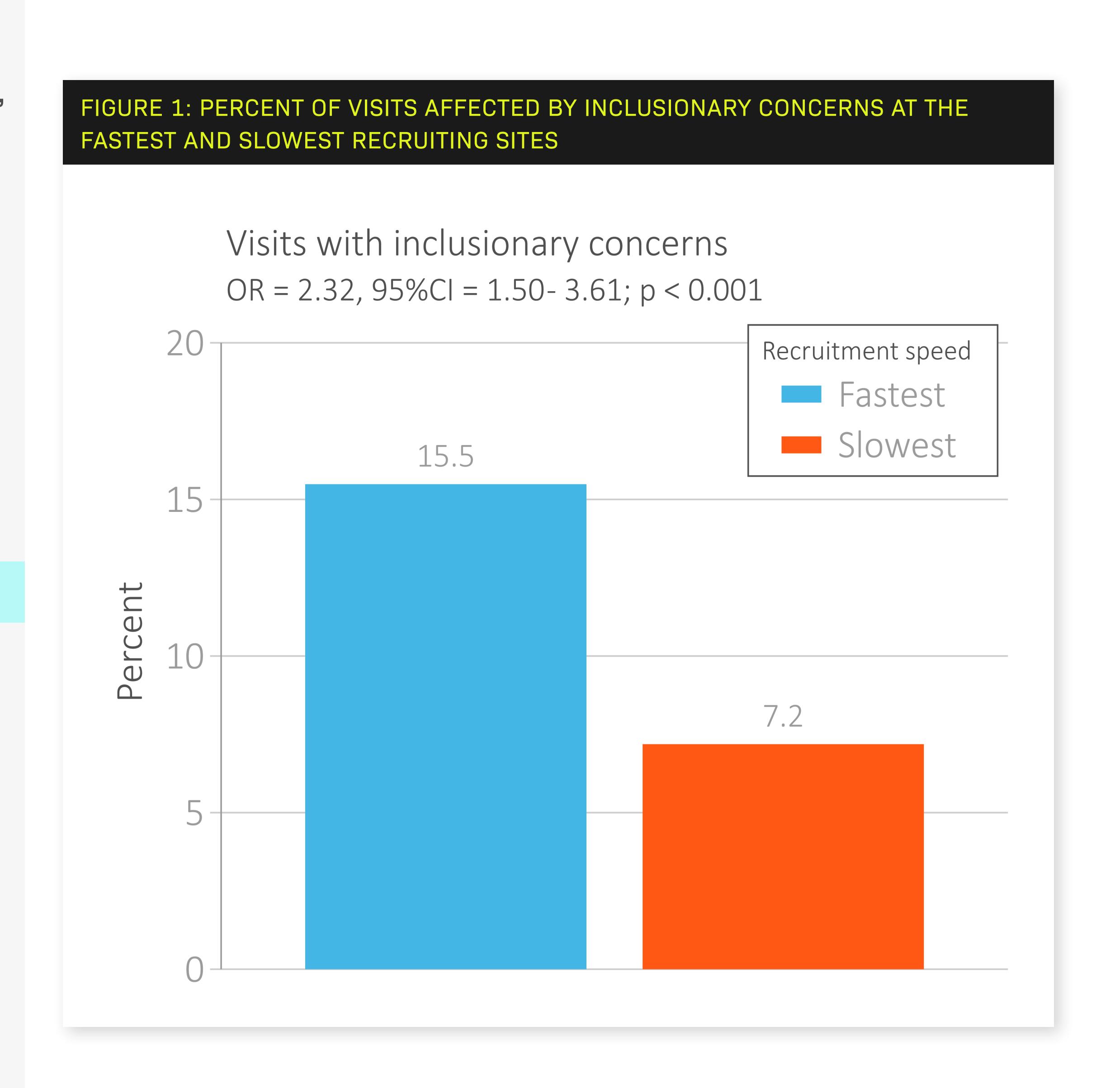
Relatively little is known about the impact, if any, of site recruitment patterns on data quality. Anecdotally we have sometimes observed an increased frequency of data quality issues related to inclusion criteria in a subset of very fast recruiting clinical trial centers. Such issues have included, for example, scores clustering around inclusionary criteria, questionable eligibility after independent audio review and unusual levels of improvement between screening and baseline. In the current analysis we assessed whether the frequency of inclusionary data quality concerns was associated with the screening rate in a pooled schizophrenia dataset.

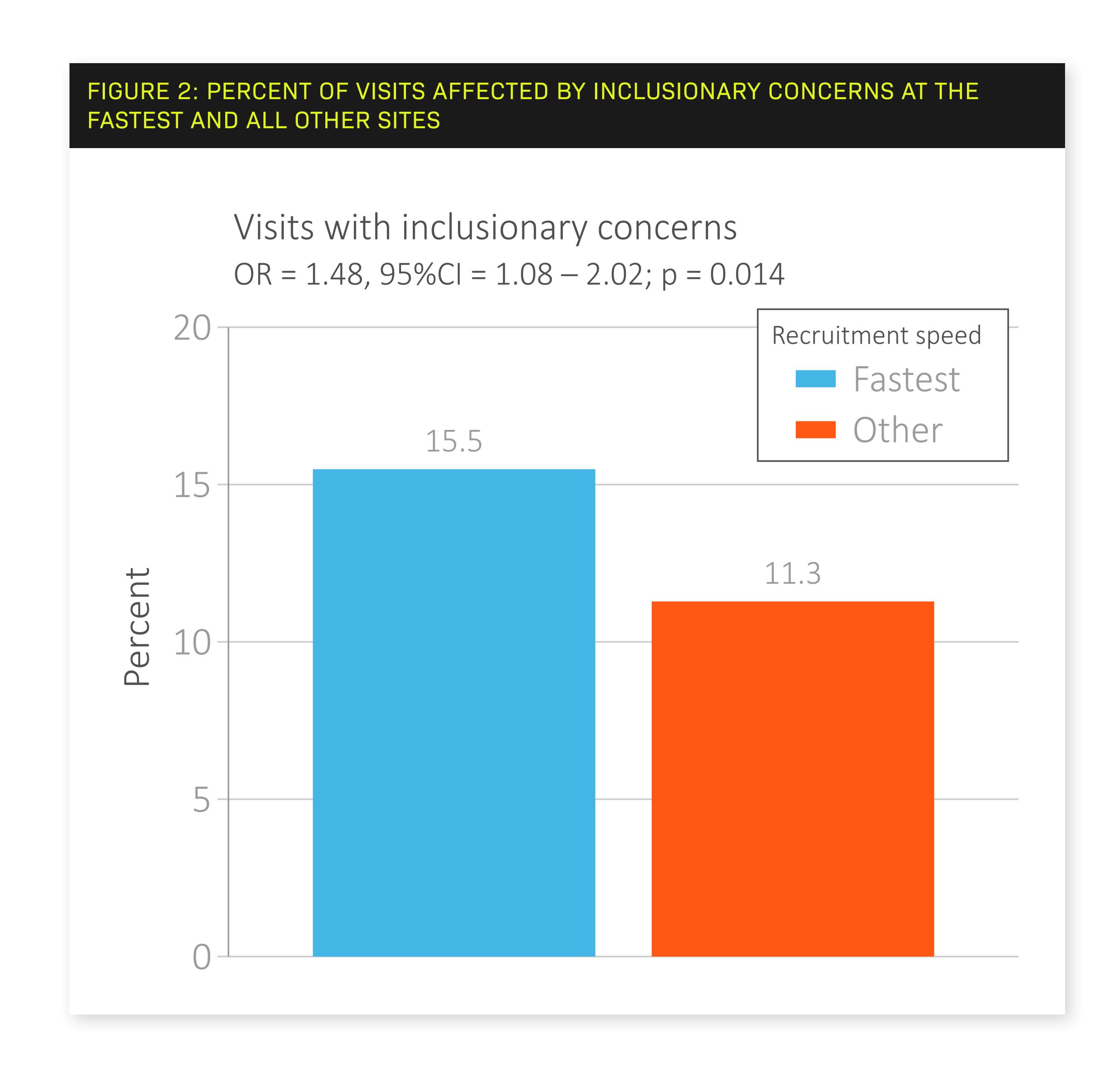
METHODS

Data were pooled from 6 acute schizophrenia studies. Due to variation from study to study and site to site in the maximum number of subjects permitted, the analysis utilized the first 10 subjects screened at each site. The time to screen these 10 subjects was calculated for each site and sites were categorized as fast recruiters if the time to screen 10 subjects was less than the 25th percentile. Two set of analyses were conducted, one where we compared the fast sites with all remaining sites and the second where the fast sites (less than 25th percentile) were compared with more slowly recruiting sites (greater than the 75th percentile). Generalized linear models were used to estimate the differences.

RESULTS

Out of a dataset of 271 sites, 109 sites screened 10 or more subjects. The time it took the sites to screen 10 subjects varied widely between the sites with the 25th percentile being 90 days and the 75th percentile 340 days. As shown in Figures 1 and 2, respectively, the odds of having an inclusionary concern were significantly increased in the fastest group compared to the slowest sites: OR: 2.32 (95%CI = 1.50 - 3.61) and to the remaining sites: OR: 2.48 (95%CI = 1.08 - 2.02).





DISCUSSION

Our preliminary analyses found an association between rapid recruitment and data quality issues such as clustering around inclusionary criteria, questionable eligibility after independent audio review and unusual levels of improvement between screening and baseline. The results are preliminary until confirmed in additional samples. However, the results are consistent with the notion that increased levels of monitoring and feedback to the fastest recruiting sites may be useful in managing data quality issues.

