Regional and Population Differences in Schizophrenia Clinical Trial Recruitment Rates

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What is the Methodological Question Being Addressed? Are there regional and population differences in recruitment rates in schizophrenia clinical trials and what are the implications for data quality and signal detection?

Introduction Recruitment rate represents one of the key operational metrics of clinical trial site performance. In schizophrenia clinical trials differences in recruitment rates have been observed anecdotally among different schizophrenic populations, regions and sites. However, systematic study to delineate these differences and their potential impact is relatively sparse. In the current analysis we pooled data from 28 schizophrenia clinical trials and assessed the impact of trial type and region. The current analysis is an initial step in exploring the relationship, if any, between a geographic region or site being an outlier with respect to recruitment rate and the quality of that region or site's data and ability to distinguish drug from placebo. Identification of at risk patterns of site recruitment could lead to strategies to mitigate their impact on data quality.

Methods All data included in the analysis were collected before January 2020 to avoid any COVID impact on the results. Recruitment rate was derived as number of subjects screened at a site into a study per week. Recruitment rate was analyzed first by region for each study type (acute, negative symptoms, maintenance, non-acute non-negative) using analysis of variance with post-hoc head to head Bonferroni corrected comparisons between regions. In the second set of analyses we specifically compared the US data with the rest of the world using a t-test.

Results Data were obtained from 17,621 subjects collected across 1,988 research sites. The average recruitment rate at a site in acute trials was 0.51 subjects per week (CI=0.48-0.55), in negative symptom trials 0.31 (CI=0.28–0.37), in maintenance trials 0.28 (CI=0.23–0.32) and in the non-acute non-negative trials 0.25 (CI=0.22–0.27), the difference between acute and non-acute trials being significant. With the exception of maintenance trials, significant regional differences were identified. In acute trials, sites in North America had a significantly increased recruitment rate compared to Asia and Eastern Europe, in negative symptom trials, both Eastern Europe and South America had significantly higher recruitment rate compared to Asia and North America, and in non-acute non-negative trials South America had significantly higher recruitment rate compared to Eastern Europe and North America. When comparing the US to the ROW data, US had significantly increased recruitment rate in acute trials, marginally increased in maintenance and significantly decreased in negative symptom trials. All at alpha = 0.05.

Conclusion Our data indicate significant differences in recruitment rates between regions. These differences were inconsistent between trial types. For example, North American sites had the highest recruitment rate in acute schizophrenia trials but one of the lowest rates in negative symptom trials. Recruitment strategies, advertising, number of ‘professional’ subjects, and other factors could possibly explain these differences. While slow recruitment rate poses a challenge to study timelines, high recruitment rate could pose a challenge to data quality and sites with high recruitment rate
should be carefully monitored for any indications of poor data quality. Future analyses will examine the relationship between site recruitment rate patterns (eg, outlier compared to other regions or sites in the same study; large numbers of subjects recruited over a short period of time) and the region or site’s data quality and ability to distinguish drug from placebo.

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Guidelines I have read and understand the Poster Guidelines

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