What are the Implications of Recruitment Source (“Clinical” or “Non-Clinical”) in Schizophrenia Trials for Successful Recruitment and Retention in Terms of Screen Failure, or Non Completion of Trial?

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### 1 | Introduction

- Recruitment is one of the greatest challenges in performing randomized controlled trials. It is a common understanding that people with schizophrenia are especially difficult to recruit into trials [1,2], and that drop out rates in drug trials with people with schizophrenia have been reported to be as high as 65.9% [3].
- Unmet medical needs lead to added pressure to develop new drugs as quickly as possible. This often results in challenging recruitment timelines. As a result, recruitment strategies move beyond the traditional, clinically-driven approaches that focus on a Principal Investigator’s (PI) patient pool and their clinical network (referred to as Clinical source), towards strategies such as online recruitment, community outreach approaches, self-referral and other approaches (hereafter termed collectively as ‘Non-Clinical’ recruitment source approaches).
- Whilst these approaches bring more potential participants to a study, it has not been clearly established what implications there are in terms of randomization rates and retention/study completion rates. This poster examines whether research participants recruited from Clinical and Non-Clinical sources differ in two aspects - levels of study randomization and of study retention/completion.

### 2 | Methods

- Recruitment source data were gathered from four Phase 3 and one Phase 4 clinical trials for new investigational medical products in schizophrenia. 3258 patients were classified as either Clinical referrals (i.e. PI’s own patient, referral from another practitioner, or research database), or Non-Clinical referrals (from advertising, internet-derived referrals, self-referrals, or outreach programs).
- Cases for which data were incomplete or missing were excluded from the analyses. Chi-square tests of independence were carried out collectively for all trials. Identifying features of the relevant trials, as well as analyses for individual trials are not reported in order to preserve trial anonymity.

### 3 | Results

**Results: Percentage of Randomized Subjects**

<table>
<thead>
<tr>
<th>Source</th>
<th>Randomized</th>
<th>Did not randomize</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical</td>
<td>24%</td>
<td>76%</td>
</tr>
<tr>
<td>Non-Clinical</td>
<td>49%</td>
<td>51%</td>
</tr>
</tbody>
</table>

- Using combined data from all trials, an association between referral source and randomization was observed, $\chi^2(1) = 166.1373, p < 0.0001$. Participants recruited from Clinical sources were significantly more likely to randomize than those recruited from Non-Clinical sources.

**Results: Percentage of Randomized Subjects that Completed the Study**

<table>
<thead>
<tr>
<th>Source</th>
<th>Completed trial</th>
<th>Early-terminated</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical</td>
<td>87%</td>
<td>13%</td>
</tr>
<tr>
<td>Non-Clinical</td>
<td>43%</td>
<td>57%</td>
</tr>
</tbody>
</table>

- Of those who randomized, participants recruited from Clinical sources were significantly more likely to complete the study than those recruited from Non-Clinical sources $\chi^2(1) = 528.5706, p < 0.0001$.

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### 4 | Conclusion /Discussion

- There was a significant difference in the distribution of study randomization and study completion between Clinical and Non-Clinical referral sources.
- A number of factors might be hypothesized to underlie these differences, amongst them implicit pre-screening by PIs of Clinical referrals, patient investment levels, or other demographic factors (e.g. differing levels of comorbidity, distance from site), etc. However, at present, available data are not of sufficient granularity to be able to answer these questions, nor are other factors such as gender, age, ethnicity, etc.
- Future data recording should allow for better encoding of relevant demographic factors. Greater consistency and accuracy of encoding of referral source would also allow for more detailed analysis of the validity of the Clinical and Non-Clinical referral source constructs.

### 5 | References


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**Disclosures**

MM, KS, and LJK are employees of Syneos Health, the Contract Research Organization responsible for the execution of all trials included in this analysis.

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