Prescreen Use of a Subject Registry in a Large Site Network:
Analysis of the First 24,000 Subjects Prescreened

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BACKGROUND

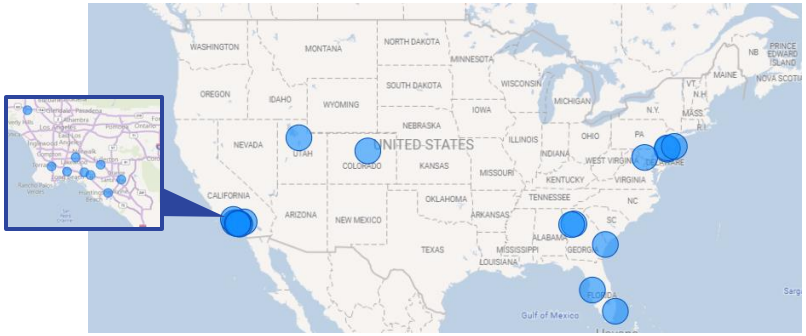
- Duplicate and professional subjects are a significant problem in clinical trials, particularly in studies with subjective endpoints, such as in CNS or pain.[1]
- Data integrity is compromised when professional subjects purposely deceive regarding inclusionary symptoms, excluded conditions, adherence to investigational product or previous study participation.[2] CTSdatabase is a subject registry which uses partial identifiers to track duplicate and professional subjects across sites and sponsors.
- These duplicate subjects may increase placebo response, may not take study medication, and almost certainly contribute to failed studies. Subject registries attempt to identify duplicate and professional subjects before randomization.[3]
- Last year we reported on the first 9 months of implementation. Now we present the data of all matches since January of 2023.[4]

OBJECTIVE

To identify and examine the use of a subject registry on the identification of duplicate, professional or otherwise inappropriate subjects at the prescreening visit for sites within CenExel, the largest therapeutically-focused site network.

METHODOLOGY

We looked at pooled study data for all subjects that prescreened at a site within the CenExel site network from January 2023 to September of 2024. We collected the number of matches (i.e., visits made by subjects at unique sites) that occurred within 30 or 90 days, categorizing them into two groups: the first group includes sites within the network ("In-Network"), while the second group combines "In-Network" matches with matches between a CenExel site and an external site ("All Matches"). Matches between "sister sites" (those where prescreening might take place at more than one location) were not included as matches in the analysis. The subject registry used was CTSdatabase, one of several commercially available subject databases.



This map illustrates the coast-to-coast presence that CenExel has as the largest therapeutically-focused site network.

OBJECTIVE

To identify and examine the use of a subject registry on the identification of duplicate, professional or otherwise inappropriate subjects at the prescreening visit for CenExel, the largest therapeutically-focused site network.

METHODS

We looked at pooled study data for all subjects that prescreened at a site within the CenExel site network from January 2023 to September of 2024. We collected the number of matches (i.e., visits made by subjects at unique sites) that occurred within 30 or 90 days, categorizing them into two groups: the first group includes sites within the network ("In-Network"), while the second group combines "In-Network" matches with matches between a CenExel site and an external site ("All Matches"). Matches between "sister sites" (those where prescreening might take place at more than one location) were not included as matches in the analysis. The subject registry used was CTSdatabase, one of several commercially available subject databases.

RESULTS

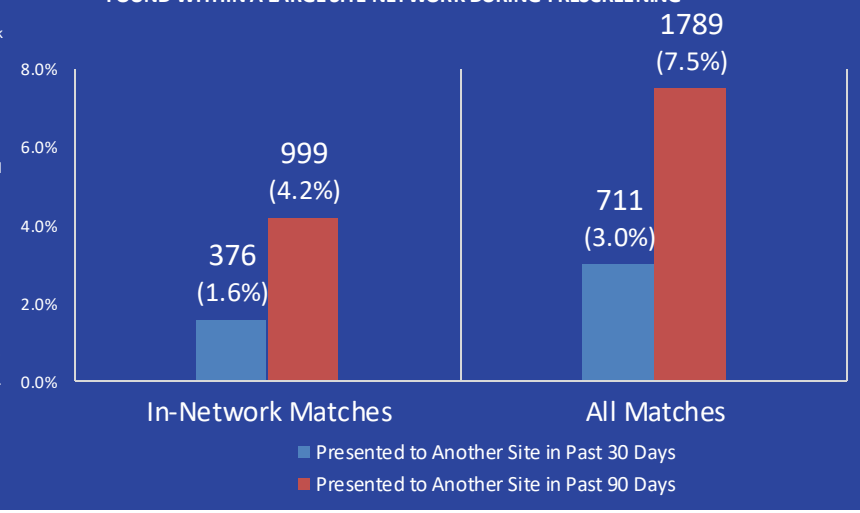
Of the 24,003 CenExel network subjects prescreened using CTSdatabase from January 2023 to September 2024, there were 376 (1.6%) unique site In-Network matches found within 30 days and 711 (3.0%) matches found within the All Matches group within 30 days. Within 90 days, there were 999 (4.2%) unique site In-Network matches and 1,789 (7.5%) unique site Cross-Network matches.

DISCUSSION

Use of the CTSdatabase subject registry during the prescreen process can eliminate duplicate and professional subjects from a large site network before they are ever screened for a study. This certainly enhances subject quality and may provides significant cost savings (in the form of screen-failures) to sponsors as well.

ANALYSIS

Of the 24,003 CenExel network subjects prescreened using CTSdatabase from January 2023 to September 2024, there were 376 (1.6%) unique site In-Network matches found within 30 days and 711 (3.0%) matches found within the All Matches group within 30 days ($p < 0.0001$). Within 90 days, there were 999 (4.2%) unique site In-Network matches and 1,789 (7.5%) unique site Cross-Network matches ($p < 0.0001$).



CONCLUSION

Use of a subject registry during the prescreening process eliminates duplicate and professional subjects from a large site network before they are ever screened for a study. These numbers have remained relatively stable over the 18 months of this analysis and highlight that many subjects (About 7% in this sample) present to other sites within a 90-day period. Such an effort requires a commitment on the part of the site network to integrate such a system at prescreen; however, this will likely reduce screen failures and improve the quality of screened subjects.

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