KNOW WHERE YOUR SUBJECTS HAVE BEEN:

Use of A Subject Registry At Prescreen In a Large Site Network

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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 to September of 2023. The number of matches, i.e. subjects who presented to a unique site, found within 30 or 90 days was collected. Matches between "sister sites", i.e. 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 11,694 CenExel network subjects prescreened using CTSdatabase from January 2023 to September 2023, 238 unique site matches (2.0%) were found for these subjects within 30 days of the prescreening visit and 624 unique site matches (5.3%) were found for these subjects within 90 days of the prescreening visit.

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 provide significant cost savings (in the form of screen-failures) to sponsors as well.

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 with regard to 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]

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.

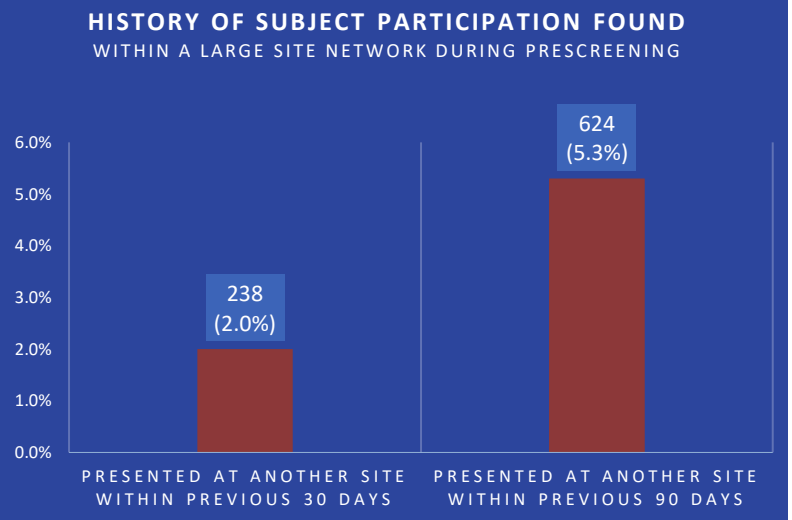
METHODOLOGY

We looked at pooled study data for all subjects that prescreened at a site within the CenExel site network from January to September of 2023. The number of matches, i.e. subjects who presented to a unique site, found within 30 or 90 days was collected. Matches between "sister sites", i.e. 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.

ANALYSIS

Of 11,694 CenExel network subjects prescreened using CTSdatabase from January 2023 – September 2023, 238 unique site matches (2.0%) were found for these subjects within 30 days of the prescreening visit and 624 unique site matches (5.3%) were found for these subjects within 90 days of the prescreening visit.



CONCLUSION

Use of the CTSdatabase subject registry during the prescreening 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 provide significant cost savings (in the form of screen-failures) to sponsors as well.

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