How Far Are Duplicate Subjects Willing To Go?

Changing Indications and Identifiers in Order to Participate in Studies at Distant Sites

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Abstract

Background & Methods

• Duplicate and professional subjects are a recognized problem in clinical trials and may represent upwards of 5% of subjects seeking to participate in CNS trials.

• Subject registries that seek to reduce this problem must be acceptable to subjects and investigators, HIPAA-compliant and secure.

• Duplicate subjects represent all adult age cohorts and both genders, but little is known about how they seek to participate in multiple studies.

• Subjects presenting at 22 participating CNS clinical trial sites in Southern California between October 31, 2011 and July 31, 2013, signed an IRB-approved authorization at prescreen to allow certain partial identifiers to be entered into CTSDatabase, a privately available subject registry. The dates when prescreening was completed of subjects who matched or nearly matched key identifiers to be ≥ 1, 107 likely to have matched by chance and entered as a second, unique site. The distances between matching sites were compared, as the frequencies with which there was a change in prescreening/diagnosis, initials, dates of birth and/or last 4 digits of Social Security Number (SSN) between sites. Distances between sites were calculated with Google Maps, using the shortest option (by available).

Results

• 3932 prescreen subjects were entered into the registry; 352 were excluded from the data set as they were re-entered at the same site (i.e., not true duplicate subjects).

• 211 unique matches (representing 422 potential duplicates) were found.

• Of these potential duplicates, 268 went to another site within 180 days, 121 within 60 days and 74 within 30 days of presenting to the first site (see Figure 1).

• Within 60 days, 74 matching subjects (1 matching subject = 2 potential duplicates) travelled to sites 25 miles apart, 14 travelled to sites 50 miles apart and 2 sites to sites separated by more than 100 miles (see Figure 2).

• 51 matching pairs had a different indication/diagnosis at the second site, 57 had a change in initials, 38 had a change in SSN (or no SSN was provided), and 9 presented with a change in date of birth at the second site (see Figures 3 and 4).

Discussion

• Placebo response is rising and there is a high failure rate in CNS Studies.6

• Duplicate and professional subjects may be more likely to respond to placebo, not take study medication and contribute to failed studies. There is a high rate of non-compliance with investigational products as measured by pharmacokinetic (PK) sampling during studies.6

• A culture of dishonesty, a declining economy, internet support for duplicate study participation and easy web-based shopping for studies have worsened the duplicate problem. Subject registries attempt to address this by preventing potential subjects who are prescreening/forcing those who have signed consent but have not yet been randomized. CTSDatabase were partial subject identifiers entered into an online registry to detect potential duplicate subjects. This registry can identify duplicate subjects who seek to avoid detection by changing sites, indications or personal identifiers. Some identifiers that cannot be easily alter, like height and gender, are also used in this registry. Other subject registries use de-identified personal information or fingerprints. In the future, changes in the identifiers may be more specific but more intrusive methods of tracking subjects may become more acceptable. Investigators and sponsors alike should be aware of problems that duplicate subjects may cause. These subjects may be willing to travel near and far, change their diagnoses and alter their personal identifiers in order to avoid detection.

Conclusions

• Duplicate and professional subjects are a significant problem and may contribute to study failure.

• Use of a subject registry is a simple way to help characterize these subjects and eliminate many fraudulent subjects before they become part of the intent-to-treat (ITT) sample.

• Some duplicate subjects are willing to travel near and far, present for different indications and alter their personal identifiers in order to avoid detection.

References


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