

## Abstract

**Background:** Duplicate and professional subjects are a growing problem in CNS trials and are not easily characterized on the basis of age, gender, race or socioeconomic status.

**Method:** Subject authorized partial identifiers of prescreening CNS subjects presenting at participating sites were entered into the CTSdatabase subject registry. All subjects and the subset of subjects who matched with subjects entered at other sites were stratified by gender and age into 10-year cohorts. These cohorts were compared with each other and with cohort data from the 2010 US Census.

**Results:** 47.8% of all subjects entered and 45.8% of all duplicates were female. Few subjects under 20 or over 70 years old were entered into the registry. 57.9% of all subjects entered in the registry and 68.8% of all duplicate subjects were between the ages of 40 and 59. The most common duplicate subject in this sample, over a quarter of all duplicates, was a male in his 40's. The likelihood of an individual member of an age-gender cohort being a duplicate, however, did not vary significantly across cohorts.

**Conclusions:** While 40-59 year olds were the most common group to be prescreened and to be duplicates in this sample, all ages and genders were represented among the duplicates. Men and women in all age groups and particularly middle-aged men in this sample, contribute to the problem of dual enrollment. Age and gender alone cannot predict which subjects are more likely to seek to enroll in multiple studies.

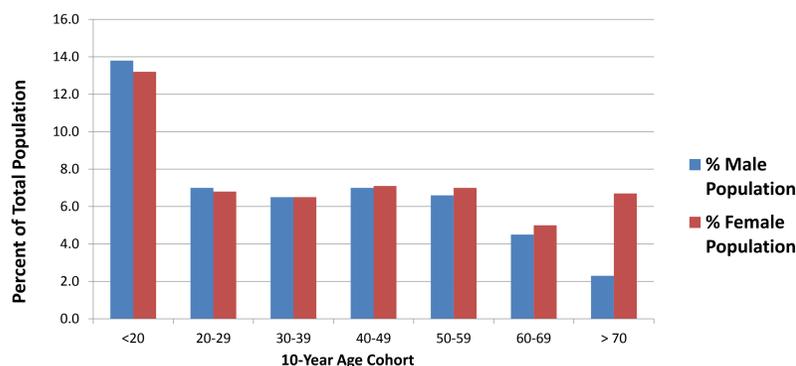
**Keywords:** Duplicate Subjects, Professional Subjects/Patients, Subject Database/Registry, Age of Duplicate Subjects, Gender of Duplicate Subjects, Duplicate Subjects Characteristics

## Background

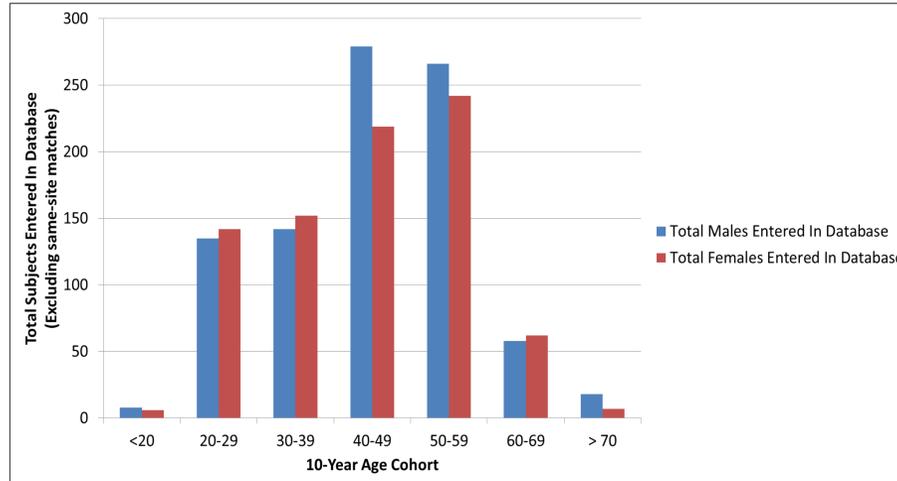
- Duplicate and professional subjects have been reported across the country, are a significant problem in clinical trials and likely to contribute to failed CNS studies.<sup>1,2</sup>
- Pharmaceutical companies that track subjects have recognized this problem and have reported duplicates in the range of 1.5-5% within their own programs.<sup>3</sup> If duplicates were tracked across pharmaceutical companies, this rate could be much higher.
- Frustrated by growing numbers of duplicate subjects, several Southern California sites agreed to register prescreens into a database to track potential CNS study subjects and communicate with one another about matched subjects.

## Methods

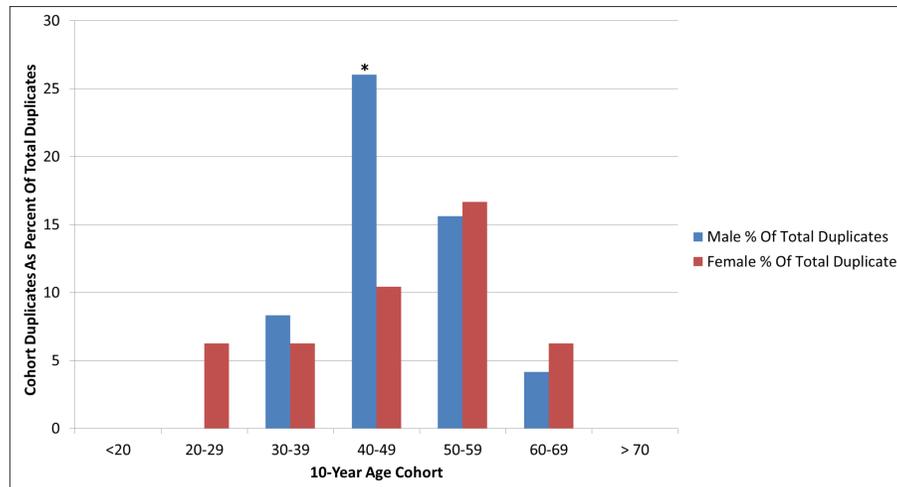
- Subjects were entered at prescreen visits by California investigative sites in Los Angeles and Orange counties participating in a collaborative effort to identify duplicate and professional patients. A privately available subject registry (CTSdatabase) was used to enter subjects who signed an IRB-approved Subject Database Authorization into the database and gather de-identified data on matches, indication, gender and age.
- 11 investigative sites participated and there were 1736 subjects entered into the registry between October 30, 2011 and December 31, 2012.
- Only virtually certain matches (those with a  $<10^{-7}$  likelihood of matching by chance) between investigative sites were included to obtain duplicate subject data. Subjects that were re-entered at the same investigative site (n= 84) were not included in the data set.



**Figure 1: Age-gender cohorts adapted from 2010 Census.** The percentages of men and women are almost equal between ages 20 and 69.



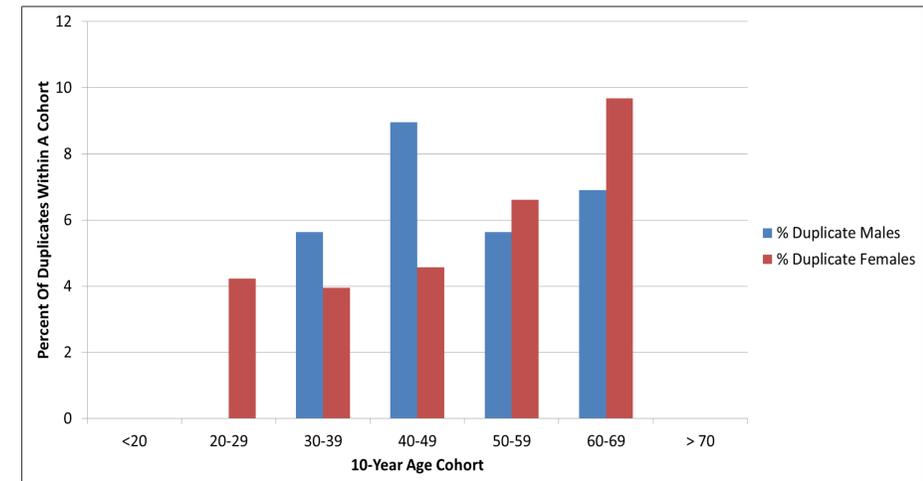
**Figure 2: Age-gender characteristics of subjects entered in database.** 98% of subjects entered were between the ages of 20 and 69.



**Figure 3: Frequency of duplicates in this sample.** \* $p < 0.001$

## Results

- The results are summarized in Figures 2-4 by 10-year age and gender cohorts.
- 40-59 year olds make up 28% of the population and males aged 40-49 comprise only 7% of the general population.<sup>4</sup>
- Figure 2 shows the numbers of subjects entered into the database, after same-site re-entries were excluded. 47.8% of the sample entered into the database and 45.8% of the duplicates found were female. 40-59 year olds comprised 57.9% of all subjects entered in the registry and 68.8% of all duplicate subjects. The vast majority of subjects entered were prescreened for depression (about 59%), Schizophrenia (about 31%) or Bipolar Disorder (about 5%).
- Figure 3 shows the percentage of duplicates in each age-gender cohort. The most common duplicate subject in this sample, over a quarter of all duplicates, was a male in his 40's. 40-49 year old males made up 26.04% of duplicate subjects but they also represented 16.07% of the subjects entered, the largest cohort.
- Figure 4 shows the percentage of duplicates within each age-gender cohort. Individual age cohorts show a trend for more duplicates in older (40-69 year olds) than younger (<40 year olds) cohorts and no males aged 20-29 were duplicates.
- The 40-49 year old male cohort is significantly larger than the other non-zero make cohorts (Chi-square 156,  $p < 0.001$ ).
- There are no other significant cohort effects.



**Figure 4: Likelihood of being a duplicate subject within each cohort.**

## Discussion

- The majority of both entered subjects and duplicate subjects were between ages 40 and 59, which is disproportionate to the 28% of this group in the general population.
- As the majority of subjects were prescreening for depression studies, middle-aged men were significantly over-represented in this sample relative to the expected patient population which has a 2:1 female predominance.<sup>5</sup>
- The economic downturn of the last 5 years, (the "Mancession") which may have disproportionately affected middle-aged men, may have contributed to this finding.<sup>6,7</sup>
- The recruitment process for clinical trials may select for a F:M ratio that more closely resembles the general population rather than the patient population.
- The demographics of our prescreen population and the disturbing number of duplicates found support the notion that subjects entered into clinical trials may not always be doing so for the right reasons and may not reflect the real patient population.<sup>8</sup>

## Conclusions

- **The demographics of subjects seeking to enroll in clinical trials do not always reflect the patient population.**
- **Men and women in all age groups and particularly middle-aged men in this sample, contribute to the problem of dual enrollment.**
- **Age and gender alone cannot predict which subjects will seek to enroll in multiple studies.**

## References

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