

Clinilabs Exceeds Target Enrollment for PK Study in Japanese and Caucasian Subjects

Business Challenge

- The study was initiated in winter when recruiting Japanese subjects is difficult
- Matching Japanese and Caucasian subjects, based on gender and smoker status, was required
- Japanese subjects had to be born in Japan with Japanese ancestry.

Solution

Clinilabs worked closely with a recruitment vendor, Iberica USA, to enroll Japanese subjects, and in coordinating the study we strived to respect the culture of the Japanese subjects.

Results

Clinilabs exceeded initial target enrollment in 12 weeks and based on that performance, the sponsor requested that we enroll six additional subjects.

OVERVIEW

Clinilabs Drug Development Corporation, the only global, full-service contract research organization (CRO) focused exclusively on central nervous system (CNS) drug development, was selected to characterize the pharmacokinetic profile of XXXX following the administration of four doses of XXXX to healthy Japanese and non-Japanese subjects aged 20 to 45 years by assessing serum concentration data over time.

Clinilabs assembled a study team that included a subject recruitment vendor, Iberica USA. The Clinilabs and Iberica teams worked closely to enroll Japanese subjects in this study. Clinilabs enrolled 11 Japanese and 11 Caucasian subjects in the trial in 12 weeks, exceeding our initial target enrollment. Based on our performance, the sponsor requested that we enroll 6 additional subjects.

“ The team’s dedication and commitment has set a positive precedent for future studies to come. ”

—Project Manager

Planned enrollment was up to 100 subjects (50 per group), with up to 10 subjects/group per dose level completing the study. The sponsor turned to Clinilabs to overcome several enrollment challenges. The study was initiated in the winter when recruiting Japanese subjects typically is more difficult. Subject matching was required (a Japanese and a Caucasian subject had to be paired based on gender and smoker status [smoker vs. non-smoker]). Japanese subjects had to be born in Japan, with Japanese parents and grandparents, and have lived less than 5 years outside of Japan.

In recognizing the importance of respecting the culture of Japanese subjects, Clinilabs provided traditional Japanese meals and entertainment to subjects while confined in the clinical research unit and translated documents to the Japanese language. Provisions also were made for the presence of a bilingual coordinator to be on site while the subjects are confined.