

CASE STUDY

A Randomized, Open-Label Study

Characterize the Pharmacokinetics and Safety of Multiple Doses of XXXX in Healthy Japanese and Non-Japanese Subjects

STUDY INFORMATION

CLINICAL PHASE: Phase I | **ENROLLMENT PERIOD:** February 2012 - May 2012

STUDY DURATION: Approximately 9 months: 28-day screening period followed by 5 treatment periods and a follow-up period. Each period consists of a 2-night/3-day inpatient period. Three of the five periods include outpatient visits.

STUDY DESIGN: 50 Japanese and 50 Caucasian subjects, male and female, healthy, aged 20-45 across multiple sites. Clinilabs was asked to enroll 10 Japanese subjects and 10 Caucasian subjects.

STUDY POPULATION: To characterize the pharmacokinetic profile of XXXX following administration of four doses of XXXX to healthy Japanese and non-Japanese subjects by assessing serum drug concentrations over time.

Clinilabs, a contract research organization (CRO), 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.

Up to 100 subjects (50 per group) are planned to be enrolled, with up to 10 subjects/group per dose level completing the 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 sponsor faced several challenges to study enrollment that they turned to Clinilabs to overcome:

- 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.

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.

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

Clinilabs has the best volunteer retention of any of the study centers due to its volunteer care and commitment.

"The team's dedication and commitment has set a positive precedent for future studies to come."

- Project Manager
