OVERVIEW

Early Development: Ethno-Bridging Study Capabilities

Ethno-bridging studies are a critical component of many clinical trials to address unique Japanese requirements for drug development. PPD's early development services for Japanese ethno-bridging studies can accelerate the clinical trial timeline and reduce costs.

Reduce costs and accelerate timelines

Detect ethnic variations in drug metabolism and/or side effects earlier

Attract prospective co-development and licensing opportunities for your product

Native Japanese Research Coordinator/Project Manager

- **15** years of clinical research experience (recruiting, enrollment, operations)
- **20+** Japanese ethno-bridging studies supported
- Leads all recruitment activities for ethno-bridging studies
- Located in Los Angeles area

Japanese Healthy Volunteer Access

- Database of **240+** Japanese volunteers and growing
- **51%** in Los Angeles and surrounding California areas
- **10%** in Las Vegas
- **9%** Other sites
- **30%** Japan, Canada or Mexico and willing to travel

PPD Early Development Highlights

Las Vegas Clinical Research Unit (CRU)

- Clinical staff fluent in Japanese and trained on customs and preferences of Japanese culture
- Japanese vendors cater authentic meals to maintain the required ethnic diet
- Study completion bonuses in addition to a competitive subject stipend
- High standards of cleanliness, adequate space, staff accessibility and professionalism

Southern California Outpatient Site

- Los Angeles area
- Accommodates out-patient visit evaluations
- Research coordinator resides here
- Virtual trial capabilities (tele-visits and home visits)

Digitally Enabled Trials

- Flexible trial solutions across the digital spectrum to increase patient access and improve the patient experience
- Telemedicine visit capabilities through our development partner Medable, Inc.
- Partnership with Science 37 enables home health visits and procedures

Site and Patient Access

- Targeted advertisements to recruit volunteers
- Access to volunteers globally that are willing to travel to CRU
- Referral program to enhance recruitment

Case Study:

Background

- The Investigational Product is a monoclonal antibody, administered as a 1-hour Intravenous Infusion.
- PPD acted as a "rescue-site" enrolling 28 Normal Healthy Volunteers, with 10 subjects comprising the Japanese Ethno-bridging arm.
- Japanese participants must have lived outside of Japan for less than 10 years at the time of screening, and descendants of four ethnic Japanese grandparents and two ethnic Japanese parents.
- The study arrived to PPD in mid-November, activities need to run through the holidays to preserve the client's FDA-submission timeline

PPD Strategy

- Leverage the Japanese-EB specialized study team
  - Extensive, and current clinical research experience
  - Comprised of native-Japanese staff members at strategic areas of study conduct
    - Study Management>Enrollment>Clinical Conduct>Administrative
  - The presence and availability of Japanese clinical staff adds an extra layer of trust and comfort to the study participants, off-setting potential intimidation from the 1-hour long drug infusion
- Review of active database for first-generation Japanese volunteers
- Regional, and demographic targeted mixed-media advertising campaign

Study Results

- The study was successfully completed, enrolling all subjects between December 2022 and January 2023
- The IRB submission was complete within 7 days of study award
- IRB approval of study protocol, and related conduction documents received within 7 days of submission

Study Enrollment Timeline

Contracted

FSFD: 01 Dec 2022

LSFD: 18 May 2023

Actual

FSFD: 01 Dec 2022

LSFD: 25 Jan 2023

PPD®