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.

### 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