Early development solutions

Ethno-bridging study capabilities

Ethno-bridging studies are a critical component of many clinical trials to address unique Japanese requirements for drug development. The PPD™ clinical research business of Thermo Fisher Scientific 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 **150+** Japanese volunteers and growing
- **75%** in Los Angeles
- **10%** in Las Vegas
- **15%** Japan, Canada or Mexico and willing to travel

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

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.
- Home health visits and procedures capabilities

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: Ethno-bridging

Background

- Investigational product is complex monoclonal antibody
- Protocol required 24 normal healthy Japanese subjects
- Wide range of subject ages needed: 18-55 years old
- To accomplish study goals in a reasonable amount of time, three cohorts of eight subjects each were built into the protocol

Strategy

- Leverage specialized research coordinator to recruit subjects quickly
  - Extensive clinical experience
  - Japanese background
  - Located in target region
- Target first generation immigrants in order to conduct study outside Japan without introducing confounding ethnic backgrounds
- Utilize native Japanese nurses at the CRU

Results

- Recruiting was very successful, and team was able to complete enrollment using only two cohorts of 12+ subjects in each
- IRB submission complete within seven days of study award
- IRB approval received within six days of submission
- This reduced the clinical timeline by more than three weeks
- 100% of Japanese subjects enrolled have interest in participating in future studies

Enrollment goal met
39
days early

Screening failure rate
11%

Early withdrawal
0%

Initial timeframe

10-07-2019
Planned first subject screen

10-15-2019
Planned first subject **Group A**: dose 8 subjects

10-30-2019
Planned first subject **Group B**: dose 8 subjects

12-04-2019
Planned last subject **Group C**: dose 8 subjects

10-03-2019
First subject screened and sponsor activation of site

10-15-2019
First subject dosed **Group A**: 13 subjects

10-26-2019
Last subject dosed **Group B**: 13 subjects

Actual timeframe

Learn more at **thermofisher.com/ppd**