

# Ethnobridging

## Supporting Global Clinical Drug Development

Ethnobridging studies are one of many clinical development services Pharmaron offers to our global customers. Ethnobridging studies can shorten the overall timelines for certain global drug development programs and are key for successful international regulatory submissions.

### Capabilities

- Access to 1<sup>st</sup> generation Japanese subjects
- Experienced native Japanese recruitment and clinical team
- Clinical Pharmacology Center in Baltimore, MD
- 96+ beds with focus on full-service early phase clinical pharmacology
- On-site CLIA/COLA accredited safety laboratory
- On-site pharmacy for extemporaneous compounding (under USP)

### What is Ethnobridging?

The term ethnobridging refers to ethnic sensitivity studies customized to support global drug development programs, with a particular focus on the Japanese population.

Ethnobridging enables the recruitment of Japanese volunteer subjects during clinical trials and assesses key factors such as **drug metabolism, PK, efficacy and safety profiles**.

By including diverse ethnicities relevant to new therapies in clinical development programs, an early and vital understanding of cultural variations associated with your lead candidate can be assessed.

Ethnobridging studies must meet strict criteria to be accepted by the regulatory authorities. Volunteers must be natives and cannot have lived away from their native country for more than 10 years. Their lifestyles, especially in terms of diet, must not have changed significantly since relocating.

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## Benefits of Undertaking Ethnobridging

- Potential to reduce international drug development timelines by approximately 5 years
- Generate data in Japanese subjects during Phase I clinical trials in the US
- Provide sufficient data for Pharmaceuticals and Medical Devices Agency (PMDA) IND filings in Japan without the need for repeating clinical studies in that specific region
- Data acquisition from relevant ethnicities in early Phase I can improve planning for later stage Phase II and III clinical trials

## Ethnobridging at Pharmaron

- Access to 1<sup>st</sup> generation Japanese subjects, with the network to recruit from a large ethnic population
- An experienced native Japanese recruitment department and clinical team
- A seamless and comfortable experience for participants during the entire process, from screening to the inpatient stay at the facility
- Support with language translation for non-English speakers
- Adherence to the appropriate native diet during the study

## Studies take place at Pharmaron's US Clinical Pharmacology Center in Baltimore, Maryland

- > 96 beds and a focus on full-service early phase clinical pharmacology
- Optimized facility layout provides the highest level of operational excellence, precision and integrity for all studies
- Clinical and scientific expertise for conducting First-in-Human, <sup>14</sup>C human ADME, DDI and vaccine/infectious disease studies
- Study procedures are supported with an on-site CLIA/COLA accredited safety lab and USP pharmacy for extemporaneous compounding
- GLP/GCP bioanalytical laboratory located nearby in Germantown, MD, for prompt PK sample and biomarker analysis

## Get Started

To learn more about our ethnobridging studies or any of our clinical services, contact [bd@pharmaron.com](mailto:bd@pharmaron.com)



[bd@pharmaron.com](mailto:bd@pharmaron.com)