CLINILABS

Ethnobridging Studies

A specialty CRO with expertise in Asian Bridging Trials

Ethnic differences have become important in the field of clinical drug development because they may impact the absorption, distribution, metabolism, or excretion (ADME) of drugs, and may be relevant to an understanding of a drug's efficacy and safety. Some regulatory agencies require that clinical trial data be obtained in specific populations in order to document drug effects in those populations. The Japanese Ministry of Health and Welfare is one such agency that seeks to ensure that drugs marketed in Japan have been tested in Japanese subjects. Pharmaceutical companies can conduct clinical trials in Japan in order to meet these requirements, but this can be rather costly. Alternatively, they may conduct "bridging studies" outside of Japan in order to document similar ADME and safety profiles in Japanese and non-Japanese subjects, allowing them to bridge Phase III data collected outside of Japan to the Japanese environment.

Phase I Units

Our phase 1 units in New York and New Jersey offer 100 beds to support ethnobridging studies, including trials that require the enrollment of Japanese, Chinese, and other specialty populations. Our clinical and operational teams are bilingual, providing subjects with the opportunity to communicate in their preferred language. Informed consent forms and other materials are translated into subjects' native languages by certified staff. Physical facilities, signage, and food choices further offer a culturally-sensitive environment in which subjects can participate in phase 1 studies.

The typical Japanese bridging study involves the assessment of cohorts of healthy Japanese subjects in comparison to cohorts of healthy non-Japanese subjects. Typically, in order to be considered for a trial, Japanese subjects must have two parents and four grandparents who also are Japanese. Non-Japanese subjects typically are Caucasian, African-American, or Hispanic. Criteria may be applied to "match" the non-Japanese subjects in a study to the Japanese participants. One such criterion often is body mass index (BMI). Other inclusion/exclusion or matching criteria may be applied.

Assessments

- Pharmacokinetic profiles (PK)
- Linear/nonlinear PK
- Pharmacodynamic effects (PD)
- Concentration-effect curve
- Therapeutic margin
- Bioavailability/bioequivalence (BA/BE)
- Protein binding
- Abuse liability

Database of Specialty Populations

- Japanese
- Chinese
- Asian (not of Japanese or Chinese descent)
- African American
- Hispanic