ALTASCIENCES
CLINICAL SERVICES

ETHNOBRIDGING

CLINICAL RESEARCH CAPABILITIES

Ethnobridging in Phase I development demonstrates equivalence between Asian and non-Asian populations. Accomplished by comparing pharmacokinetics of the drug after administration to both ethnic groups, this strategy promotes a reduction in cost and development time, allowing sponsors to recruit patients in "global" safety and efficacy trials (Phase II-III) without repeating Phase I development in that region and population.

Altasciences recruits from a large ethnic population in Southern California and have a dedicated Asian recruitment and outreach department to liaise with our participants. With experience conducting over 240 ethnobridging studies since 2004, we offer two potential solutions:

- A single study once the target doses for the global study have been identified
- The addition of Asian subjects to the first-in-human (FIH) study

Altasciences delivers a fully integrated, seamless offering for your ethnobridging trials, with large and small molecule bioanalytical laboratories and comprehensive research support services.

Research Highlights

- Average ~750 Asian participants recruited yearly
- Over 9,000 Asian participants in database
- Bilingual and trilingual recruiting, marketing, and clinical operations staff

Over **15,000**
Asian Individuals in Participant Database

Approvals for Large Global Sponsor

Conducted the largest ethnobridging study ever performed which led to a label change stating that, unlike Caucasians, Asians needed to be administered a half-dose.

16
Compounds tested

→

11
Accepted by PMDA

5
Awaiting sponsor or regulatory action

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ETHNOBRIDGING CASE STUDY

The following case study highlights successful multi-ethnic subject enrollment, with data approval by the PMDA.

Large Volume of Caucasian, Japanese, and Han Chinese Subjects

The study consisted of multiple-dose pharmacokinetics and safety of the co-administration of **** and **** in healthy Han Chinese (CH), Japanese (J), and Caucasian(C) adult subjects.

- Study Population: Normal healthy volunteers
- Study type: Japanese bridging
- Target Enrollment: 135 subjects
- Enrollment: 45 C, 45 J, 45 CH
- Total Screening Duration: 35 days

The following schematic shows treatment assignments based on ethnicity, precisely completed before treatment.

	Dosing Schematic		Arm 1 N=75			Arm 2 N=60		
Cohort #	Day 1-7	Day 8-14	CAUC.	JP	CH	CAUC.	JP	CH
Cohort 1	Dose A	Dose A + B	5	5	5	4	4	4
Cohort 2	Dose C	Dose C + D	5	5	5	4	4	4
Cohort 3	Dose E	Dose E + F	5	5	5	4	4	4
Cohort 4	Dose G	Dose G + H	5	5	5	4	4	4
Cohort 5	Dose I	Dose I + J	5	5	5	4	4	4
			25	25	25	20	20	20

135

Multi-ethnic subjects enrolled

Broad Ethnobridging Experience

Examples of studies conducted

Type of Bridging and Other Criteria Caucasian (C)/Chinese (Ch)/Japanese (J)	First Subject Dosed	Last Subject Out	# of Subjects
Japanese (First generation, born in Japan and has not lived outside of Japan for < 5 years)/Caucasian (H incl.) age 18-55	9/27/16	11/10/16	40 (20J+20C)
Japanese (First generation, born in Japan and has not lived outside of Japan for < 5 years or second generation.)/Chinese (First generation, born in China and has not lived outside of China < 5 years or second generation)	5/27/15	9/29/15	48 (36J+12Ch)
Japanese (First generation only) age 18 - 55	10/5/17	6/12/18	32 (J)
Japanese (First generation, born in Japan and has not lived outside of Japan for > 10 years)/Caucasian age 18-75	9/28/17	2/27/18	47 (27J+20C)
Japanese (First generation, born in Japan and has not lived outside of Japan for < 5 years)/Non-Asian age 18-55	8/10/17	10/9/17	60 (30J+30 Non-Asian)

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