ALTASCIENCES

ETHNOBRIDGING
CLINICAL TRIALS

Ethnobridging studies evaluate drug exposure differences between Asian and non-Asian populations by comparing the pharmacokinetics (PK) of the investigational drug across both groups. These Phase I studies provide the necessary data to include Asian populations in global safety and efficacy Phase II to III trials, without repeating Phase I programs in those regions.

Why Choose Us for Your Ethnobridging Studies?

30+
years of experience

250+
ethnobridging studies completed

LARGEST ETHNOBRIDGING STUDY
conducted to date, resulting in a U.S. label update, recommending a 50% dose reduction for Asian patients.

Our experts will help safely accelerate your drug development timelines and increase asset value through two flexible solutions:

- **Standalone Asian Ethnobridging Studies:** Conducted in the U.S. after identifying target doses for your global program.
- **Integrated Studies:** Including Asian participants in first-in-human studies or other PK-focused clinical pharmacology trials performed in the U.S.

A Turnkey Solution for Ethnobridging Clinical Trials

Our approach to ethnobridging clinical trials begins in Phase I. We will manage every aspect of your trial from start to finish, with comprehensive services:

- **Study Design:** We collaborate with you to develop a study that meets scientific objectives and aligns with global regulatory expectations.
- **Regulatory Consulting:** Our team is well-versed in international and regional regulatory requirements, including those of the PMDA (Japan), SFDA (China), ICH E5, and ICH E17.
- **Clinical Conduct:** Our state-of-the-art clinic is fully equipped, with expert teams managing dosing, sampling, and intensive monitoring.

contact@altasciences.com
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Ethnic Population

Situated within a large metropolitan area, our clinical pharmacology unit in Los Angeles is able to recruit from a diverse ethnic population. We prioritize participant experience with culturally tailored support from recruitment to dosing for maximized engagement and retention. This enables you to receive reliable and on-time data.

To ensure **cultural sensitivity and optimal comfort** for the duration of your study, we provide participants with:

- native-speaking recruitment teams
- language and cultural support during the study
- ethnic-specific meals when permitted by protocol
- multilingual study documents, including informed consent forms (ICFs)

~800
Asian participants recruited yearly

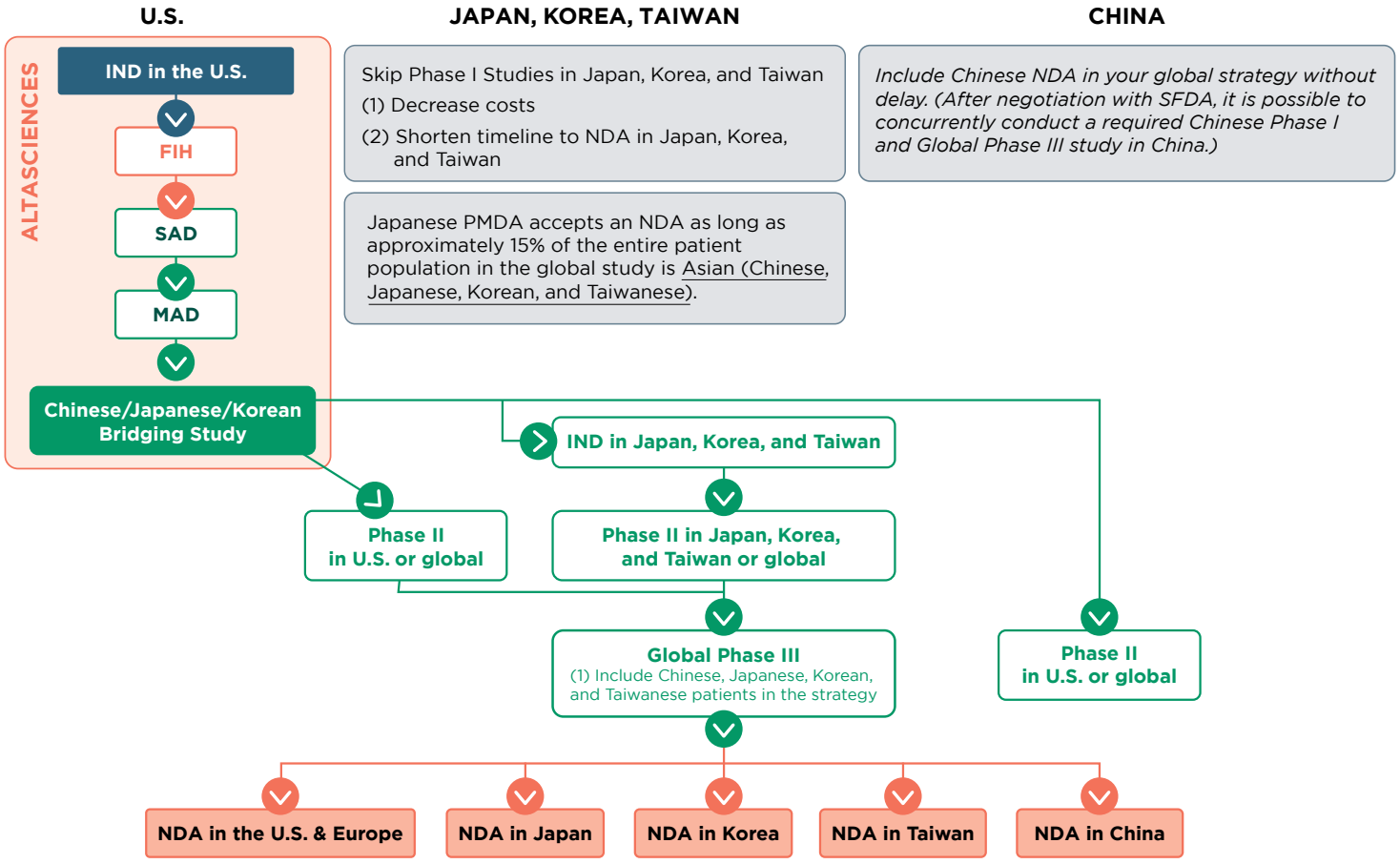
12,000+
Asian participants in our database

MULTILINGUAL STAFF
across all roles and functions

Accelerated Global Drug Development Timeline

By studying all required populations simultaneously, we significantly shorten drug development timelines, compared to traditional approaches. This strategy will help you safely speed up regional development and regulatory submissions worldwide.

Simultaneous Global Drug Development



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