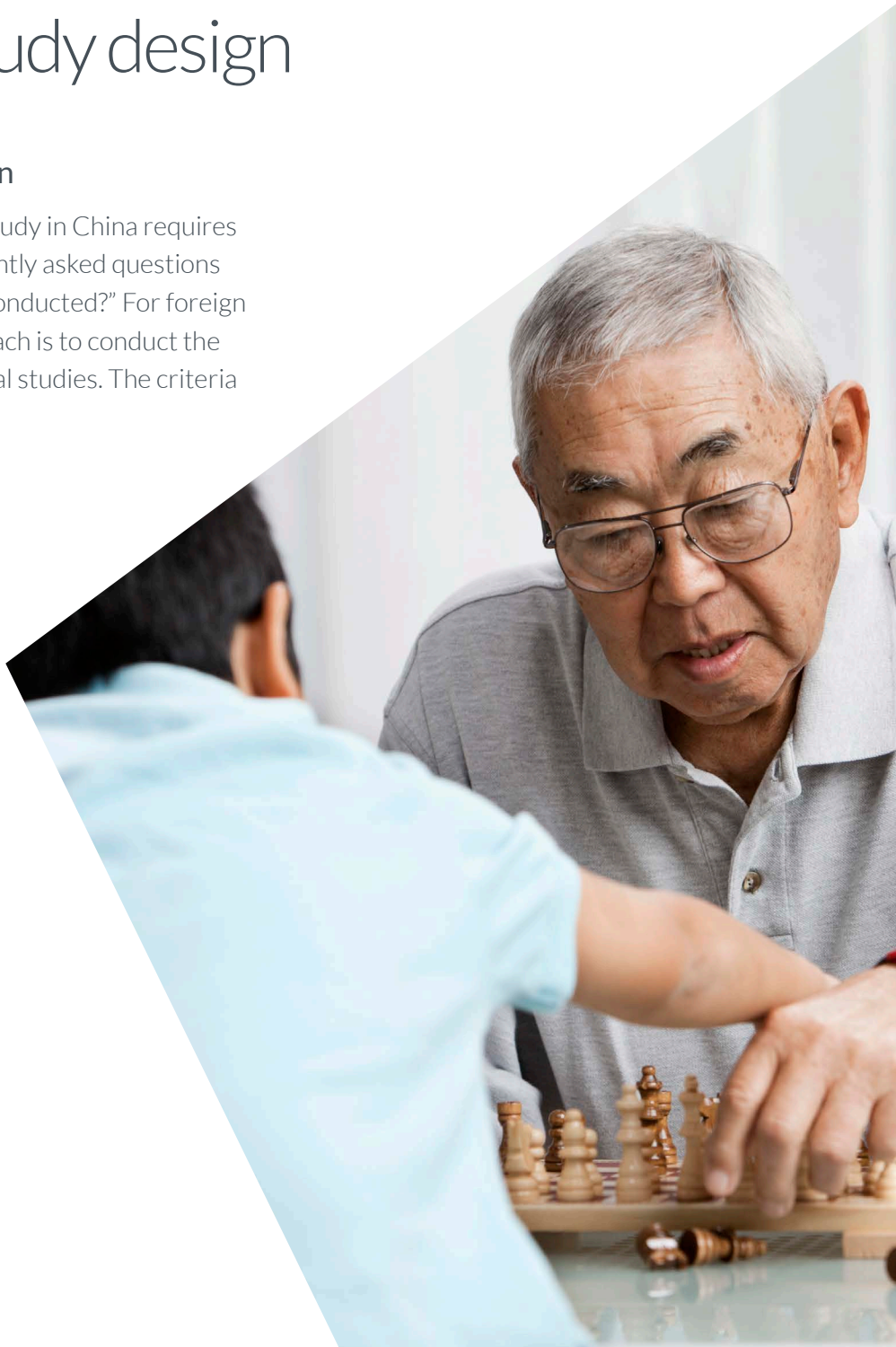


Navigating China's market entry: Bridging studies for foreign medical product registration – optimizing China PK bridging study design

China PK bridging study design

When conducting a pivotal patient study in China requires a Chinese PK study, the most frequently asked questions are, “How and when should this be conducted?” For foreign medical products, the optimal approach is to conduct the China PK study in parallel with pivotal studies. The criteria for this approach are as follows:

1. The product has low risks of ethnicity difference as per ICH E5 (preferably with preliminary Chinese/Asian data analysis)
2. Target indication fulfills the unmet medical needs in China
3. The product has good safety and efficacy profiles demonstrated by the completed global early phase studies (e.g., no critical safety concern, wide therapeutic window, and good efficacy)



Upon satisfying the three criteria, companies may initiate consultations with the China CDE regarding concurrent implementation of Chinese PK studies alongside pivotal or Phase II studies. In general, there are two approaches based on ethnicity differences:

Study design		Population	Participant number	Remark
1. Separate China PK study in parallel with pivotal study		Healthy volunteers	8-12 per dose level (assuming low exposure variability)	<ul style="list-style-type: none"> ➤ Standard approach ➤ Need to plan China study earlier
2. China PK embedded in pivotal study	Intensive PK sampling cohort in pivotal study	Participants with target indication	Selected 8-12 (unblinded) or 16-24 (double blinded)	<ul style="list-style-type: none"> ➤ Case-by-case discussion with the China CDE at pre-CTA consultation period ➤ The China CDE might ask completing the intensive PK cohort before initiating the pivotal study
	Pop PK with sparse PK sampling in pivotal study	Participant with target indication	Sparse PK for majority of participants	<ul style="list-style-type: none"> ➤ PopPK may be suitable for products with high unmet needs where intensive PK sampling is unfeasible

Incorporating Chinese participants into global early-phase clinical trials is a critical strategic consideration for pharmaceutical companies aiming to optimize their drug development process and expedite market entry in China. Parexel’s Early-Phase Clinical Units in Los Angeles and London are well-positioned to conduct this type of PK study, given its long-history, strong capability, and extensive experience in recruiting Chinese, Asian, and Caucasian participants.

Key considerations for bridging study design

The following criteria serve as prerequisites for conducting a bridging study:

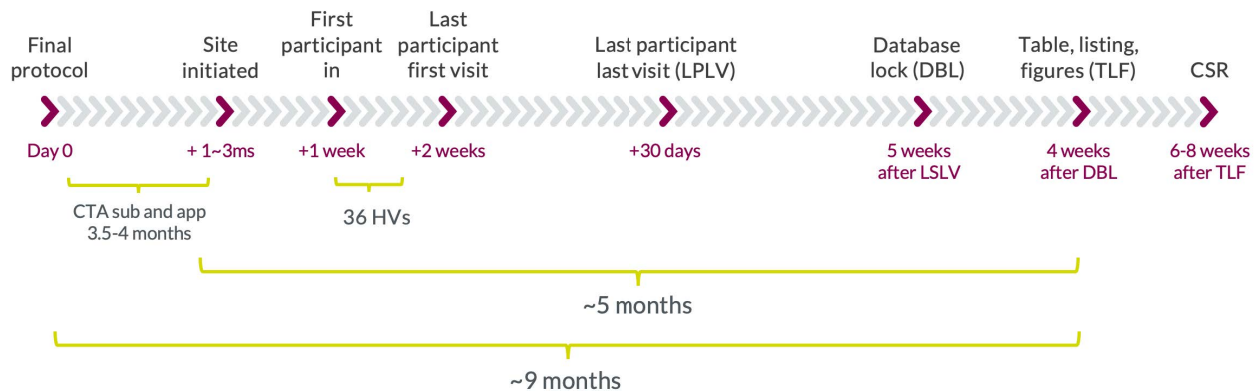
- 1. Global pivotal study success:** Successful outcomes in global pivotal studies are essential for China's acceptance and recognition of bridging study results.
- 2. Dosage/regimen applicability:** Evaluating the appropriateness and efficacy of the dosage and treatment regimen for the Chinese population.
- 3. Safety and efficacy profile extrapolation:** Able to extrapolate from global data to Chinese
- 4. Global pivotal study design:** The strategic design of globally pivotal studies plays a critical role in facilitating the acceptance of Chinese bridging study outcomes.
- 5. Understanding of the disease:** A comprehensive understanding of disease characteristics, including progression patterns and diagnostic criteria, is crucial when extrapolating from global to Chinese populations.

Upon fulfillment of all prerequisites, consider the following comprehensive strategies to streamline China bridging study:

- 1. Controlled vs. single-arm design:** Deciding between a controlled study design and a single-arm design in China study.
- 2. Duration of follow-up:** Considering the length of participant follow-up, with options for extended or shorten the follow-up period in China study.
- 3. Clinical endpoints vs. surrogate endpoints:** Choosing between clinical endpoints and alternative (surrogate) endpoints in China study.
- 4. Trend analysis:** Analyzing trends in the data instead of full power study in China to recruit less participants.

How long would a China standalone PK bridging study take?

If a China standalone PK bridging study is required, the typical study timeline is as follows:



Note: the proposed timeline based on the following study design assumptions: enroll 36 healthy volunteers (12 for each group) from single Parexel Partner Phase I site for 2 weeks. The study includes single and multiple dose administration with PK and safety assessments through Day 24 and follow up on Day 30.

Summary

Successful registration of foreign medical products in China requires a strategic approach that balances global development goals with local regulatory requirements. By carefully considering ethnicity sensitivity, implementing appropriate bridging studies, and engaging in early consultation with the China CDE, companies can optimize their development pathways and increase their chances of simultaneous global and Chinese market entry.



With Heart™

Ready to discuss your plan to conduct China bridging study? Our ex-NMPA/CDE regulators are always available for a conversation..

Connect with us to learn more.

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