Parexel Early Phase Services in China

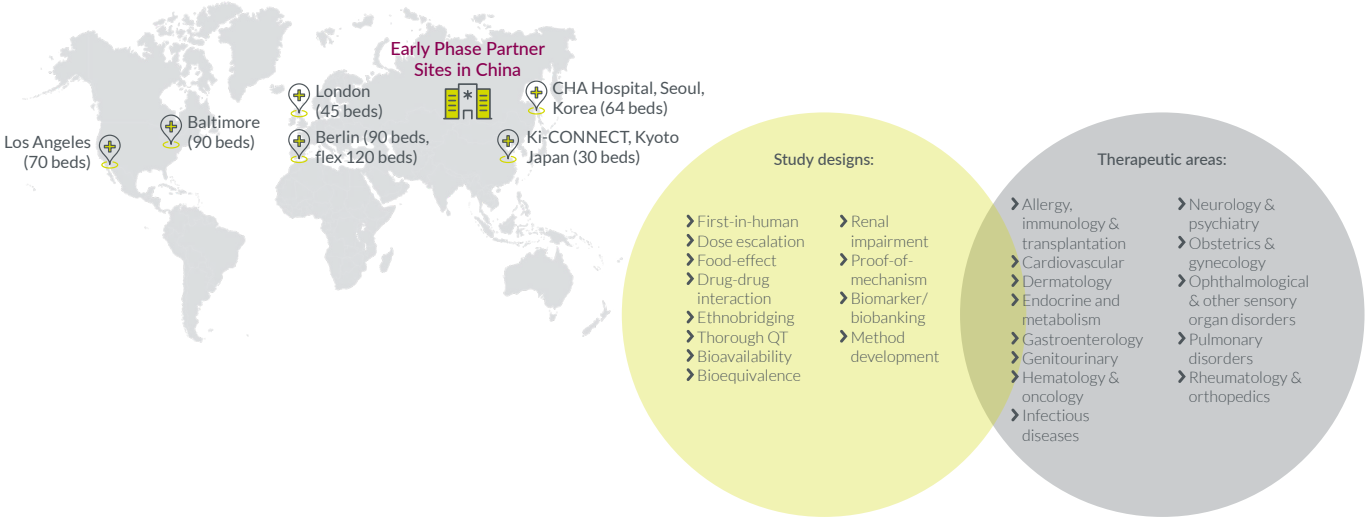
A leader in implementing and accelerating early phase studies

Parexel provides one-stop shop with mature model for Early Phase Services

Parexel offers extensive services pertinent to all aspects of early phase clinical studies including IND support, study design, interpretation of phase I/IIa study results, and intensively support on the NDA in different regions. We leverage our talented regulatory, scientific, operational, medical expertise, and clinical site capacity to help companies reach important development milestones quickly and make better, faster Proof of Concept (PoC) decisions

Parexel global early phase capability

- Dedicated team covering all aspects of early phase trials
- Parexel owns four Early Phase Clinical Units (EPCUs) in the US and EU/UK, conducts approximate 120 clinical pharmacology trials each year in the global areas
- Strategic early phase partner sites in APAC working seamlessly with Parexel scientific, project management, and operation team in all indications to achieve delivering with short timeline and high trial quality

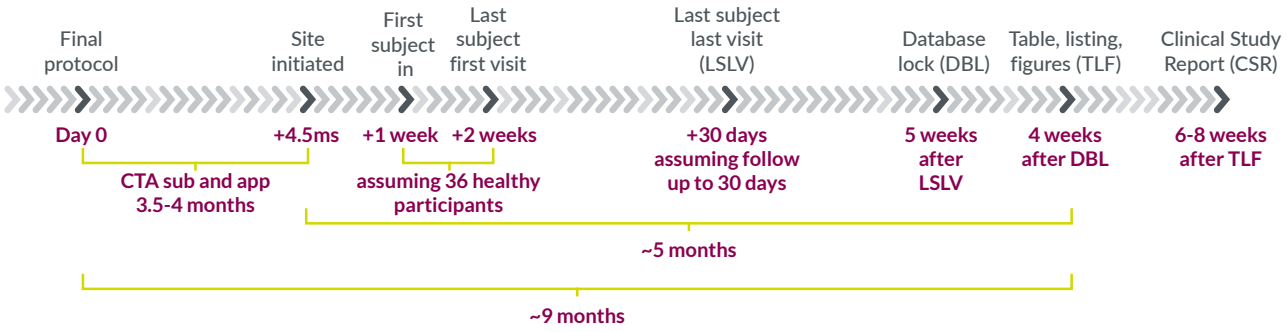


parexel

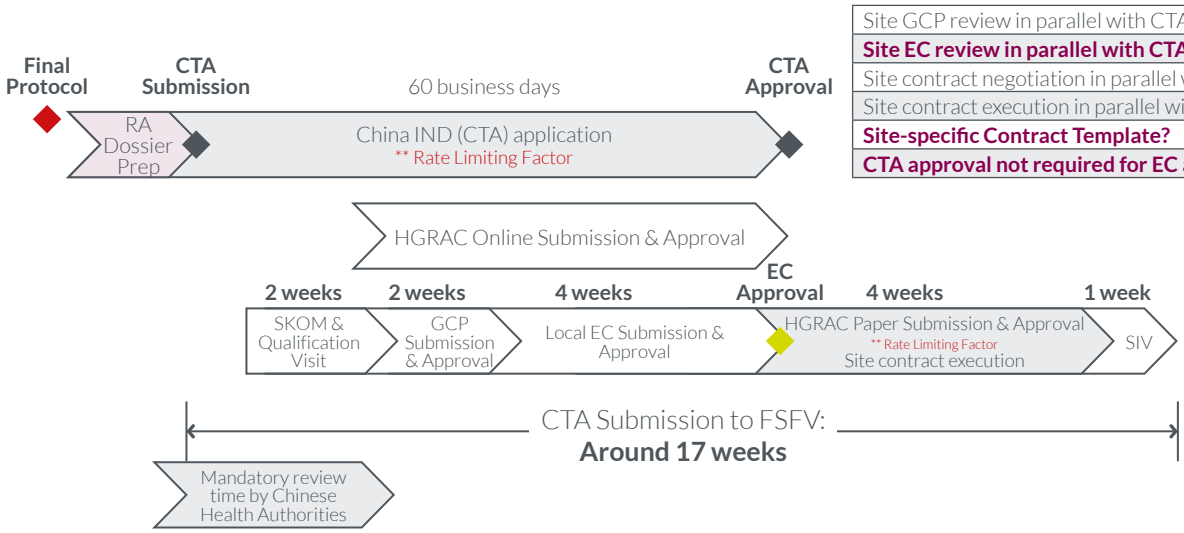
Our expertise on China phase 1 studies

With our experience, we can help you achieve promote phase 1 study conduction with top quality results fulfilling both local and global regulatory requirements

› Study timelines for a typical China phase 1 study (non-oncology), in total of 9 months from protocol finalization to table, listing, figures (TFLs) available



› Parexel achieves 98.8% Human Generic Resource Administration of China (HGRAC) application passing rate



Site GCP review in parallel with CTA review?	✓
Site EC review in parallel with CTA review?	✓
Site contract negotiation in parallel with EC submission?	✓
Site contract execution in parallel with HGRAC Approval?	✓
Site-specific Contract Template?	✓
CTA approval not required for EC approval letter issue	✓

CTA: Clinical Trial Application; EC: Ethics Committee; HGRAC: Human Genetic Resource Administration of China; SIV: Site Initiation Visit; SKOM: Sponsor kick-off meeting

Seamless site start-up (SSU) timelines - in 17 weeks

All site start up process arranged in parallel with regulatory applications

Liaison with top phase 1 sites in China, easy & prioritized connections with Key Opinion Leaders (KOLs)

Parexel early phase partner sites in China are guaranteed as

- National Medical Products Administration (NMPA) certified phase 1 clinical units affiliated to the hospitals
- High reputation sites passed all NMPA inspections on completed phase 1 studies
- Site strongly supported by Parexel global level technical and quality system

General advantages in Parexel early phase partner sites

- Quick site start-up. No site feasibility, simplified site qualification process, available site contract template
- EC review in parallel with CTA review
- Quick KOL consultation
- Prioritized beds. Commitment to all Parexel's phase 1 studies
- Healthy volunteer pool & special population (patient) access

China early phase study experiences in the past 3 years

- First-in-human (FIH) study for innovative drug
- Dose escalation study – seamless connection with Australian/US/EU FIH study
- PK bridging study for China registration purpose
- Complex clinical pharmacology study (e.g., glucose clamp)
- Food effect study
- Biosimilar study
- PK study in patients
- Renal/hepatic impairment study

~1,200

Healthy volunteers and patients enrolled

~40

Early phase studies conducted in China

For more information regarding our early phase solutions, visit:
Early Phase Clinical Trials | Early Phase Services | Parexel