Article

First-In-Human Trials in Malaysia: Regulatory and Clinical Readiness

Insights on regulatory timelines and operational readiness for First-In-Human (FIH) trials in Malaysia

Malaysia is an emerging hub for early-phase clinical development. With a population of over 34 million, Malaysia's ethnogenetic diversity provides a natural stratification for early-phase clinical trials, enabling meaningful pharmacogenetic insights within a single regulatory and operational framework.

Insights from a recent webinar, "First-In-Human Trials in Malaysia: Regulatory and Clinical Readiness" highlight several key considerations shaping the country's readiness for early-phase studies — spanning site capabilities, regulatory expectations, and operational efficiencies.

Regulatory considerations and timelines

How long is the timeline for regulatory and Ethics Committee (EC) submission and approval for FIH studies, and the expected approval timeframe for substantial amendments?

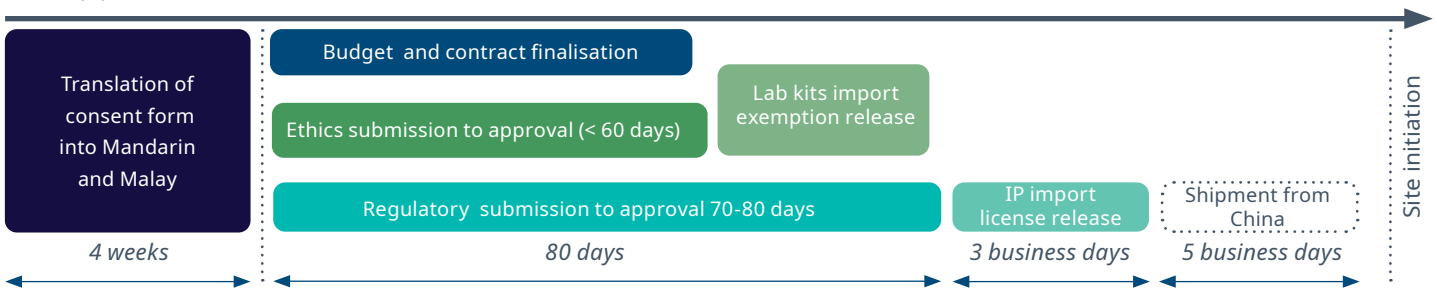
In Malaysia, there are two key regulatory pathways, Clinical Trial Import License (CTIL) and Clinical Trial Exemption (CTX).

~45 working days	over **<60** days	**~4** months
Regulatory approval by National Pharmaceutical Regulatory Agency (NPRA)	Ethics approval by the Ethics Committee	Start-up timeline from initiation to trial start

Once regulatory approval is obtained, import licenses are issued within **3 working days,** and shipping investigational products from China usually takes about **5 working days.**

Start-up duration: From document finalization to initiation

Start-up process flow:



Total = 4 months

Assumption — national level contract template used without revision

Amendments

NPRA does not differentiate between major and minor changes post-approval. For updates such as protocol amendments, Investigator Brochure updates, or Investigational Medicinal Product Dossier (IMPD) changes, sponsors only need to notify NPRA — no additional approval is required.

However, changes such as increasing drug quantity, adding study sites, or changing the principal investigator require NPRA approval, with a timeline of **within 15 working days.**

Supporting factors for efficiency

- Parallel submission for regulatory and ethics approval
- Early preparation for Informed Consent Form as translation into English, Malay, and Mandarin typically takes ~4 weeks
- Standard contracts can reduce legal review to ~48 hours

Documents

- Protocol, investigator's brochure, and informed consent forms
- Proof of insurance and Phase I unit accreditation are additional requirements for FIH studies
- Applications must be submitted by a licensed pharmacist in Malaysia

Fast-track review may be granted for new product applications. Phase III pivotal clinical trials conducted locally with a minimum of 10% of total randomized subjects enrolled at Malaysian study sites

For FIH studies, what are the key requirements in Malaysia for safety evaluation especially on the starting dose and risk mitigation?

NPRA places emphasis on thorough **preclinical risk assessment.** Sponsors must provide **scientific justification** for the starting dose and implement appropriate risk mitigation measures.

All potential severe toxicities observed in animal studies must be evaluated, and mitigation strategies must be included in the protocol which should also define the **sentinel dosing, dose escalation strategies,** and **clear stopping rules.**

Where do delays typically happen during the study start-up and how to avoid them?

Delays are often driven by late amendments to study documents, budgets, or contract language after review cycles have commenced. To ensure start-up activities can be completed within planned regulatory and ethics review timeline, provide **mature documents early, limiting non-essential revisions on contracts or leveraging available national contract templates** which eliminate the need for contract negotiation.

Malaysia also benefits from a centralized framework through **Clinical Research Malaysia (CRM)**, which facilitates contract review and execution with review turnaround times typically achieved within **two weeks**. This streamlined approach supports efficient study start-up.

Malaysia's operational readiness for early-phase studies

What are Malaysia's key advantages compared to other markets, and the current state of its clinical readiness?

Patient diversity: Multi-ethnic population enables meaningful pharmacogenomic insights

Full-phase capability: Proven infrastructure and experience across **FIH** to **Phase IV** studies

Cost-effectiveness: Competitive cost structure compared to countries such as the United States, Australia and Singapore, paired with relatively fast timelines

What makes Malaysia operationally effective for clinical trials?

A well-coordinated ecosystem that supports efficiency and initiatives to strengthen early-phase development.

- **Centralized contracting model** for Ministry of Health sites, providing a single legal review pathway that accelerates contract execution across participating sites.
- **Operational efficiency** from study start-up to delivery, enabled by Malaysia's mature research infrastructure and well-established regulatory environment.
- **Rigorous accreditation standards** for early-phase units, fostering high-quality research conduct and robust clinical development capabilities.

What infrastructure supports FIH trial delivery in Malaysia?

Two accredited centres in Malaysia that can conduct FIH trials. Only FIH trials require special accreditation which ensures quality and safety standards

60 experienced clinical research sites, offering access to mature clinical research landscape

The FIH centres are supported by dedicated clinical research units and internationally trained investigators, providing the infrastructure and expertise required for robust clinical oversight. The quality of early-phase research is further reinforced through routine inspections by the national regulatory authority, helping to ensure compliance with international standards and the high-quality delivery of clinical trials.

CONCLUSION

Malaysia's growing readiness for early-phase and FIH trials reflects a combination of robust regulatory frameworks, diverse population, site capabilities, and localized support. For sponsors considering Asia Pacific, the country could be evaluated as part of a broader clinical development strategy.

For additional information, IQVIA has recently published a white paper, **"Malaysia: The New Destination for Early Phase Trials"**, highlighting the country's unique proposition. Connect with IQVIA to discuss specific study needs and opportunities in the market.

Scan QR code to download paper

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