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# Navigating China IIT Importation Without Losing the Speed Advantage

## Author Expertise

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## China IITs Are Unique and Operationally Challenging Across the Clinical Supply Chain

China IITs can offer advanced therapy sponsors a faster and more cost-efficient path to early clinical data. But those advantages can disappear quickly when importation and clinical supply planning are treated as downstream logistics activities rather than part of the study strategy.

Unlike the U.S. and Europe, clinical trial authorization in China does not necessarily resolve the requirements for importing investigational material. Customs clearance, Importer of Record responsibilities, hospital capabilities, documentation, and—in some advanced therapy settings—patient-specific timing can all become critical-path dependencies. Recent trends indicate that Chinese Customs authorities have become less flexible, particularly for clinical trial materials imported from outside China. Furthermore, for advanced therapy modalities there is growing pressure to align import timing with patient-specific informed consent, adding complexity to supply chain planning.

## Expertise and Partnership Are Essential

Many sponsors, particularly those new to China IIT processes, underestimate the complexity of both the clinical execution model and the physical importation and logistics process of DP finished goods or investigational materials. In practice, successful execution requires tight coordination between sponsors, CROs, hospitals/sites, logistics providers, and local regulatory experts.

For example, advanced therapy companies have recently encountered situations in which:

- Chinese Customs required additional documentation proving intended clinical use and drug origin
- Hospitals/sites declined to act as Importer of Record due to licensing, tax, liability, and limited global trade compliance capability concerns
- CROs had strong clinical capabilities but lacked experience navigating import requirements

In these cases, delays were often driven not by a single missing document, but by misalignment across regulatory, clinical, customs, hospital/site, and logistics stakeholders.

However, operational trade-offs remain. While sponsors often prefer to import larger batches for efficiency, evolving expectations, particularly for advanced therapies such as cell and gene therapy (CGT), may require patient-specific importation tied to informed consent, placing international shipping directly on the treatment administration critical path.

As sponsors evaluate China IIT strategies, these evolving operational realities highlight that execution risk extends well beyond clinical study design. Regulatory uncertainty, import requirements, and partner capabilities increasingly influence study feasibility, timelines, and overall program success.

# Challenges and Risks

## The Regulatory Framework is Becoming Clearer, but Execution Remains Fluid

IITs have historically operated in a legal gray zone and do not fit neatly within China's traditional product-focused regulatory framework, which was primarily designed around industry-sponsored registration trials.

However, China recently introduced the Regulations on the Administration of Clinical Research and Translational Application of New Biomedical Technologies (State Council Decree No. 818), establishing a more formal national framework for the clinical research and translational application of new biomedical technologies, including advanced therapies such as CGT. While the regulation provides greater structure and oversight for IITs and translational medicine activities, practical implementation, impact, and interpretation across logistics and importation continue to evolve.



### Clinical Approval Does Not Eliminate Import Risk.

Documentation and Importer of Record (IOR) requirements are extensive and may vary by circumstance and point of entry; customs clearance is not guaranteed even with preparation.



### Your China Strategy is Only as Strong as Your Local Partners.

CROs, logistics providers, and hospitals/sites play critical roles but may have varied levels of experience with China IITs.



### For CGT, Logistics Can Become Part of the Treatment Critical Path.

Cold chain management, labeling, and chain-of-custody requirements are tightly enforced and subject to inspection.



### Patient-Specific Timing Can Put Logistics on the Critical Path.

Potential requirements to align import timing with patient consent may reduce flexibility and increase execution risk.



### Ambiguous Ownership Creates Avoidable Compliance Exposure.

Lack of clear accountability within IITs increases exposure to misuse or regulatory non-compliance.



# What to do

Realizing the speed and cost advantages of China IITs requires sponsors to address supply chain, importation, and logistics considerations early and integrate them into the broader clinical execution strategy.

Importation should not be treated as a downstream activity; decisions regarding import pathways, local partner roles, documentation, product handling, and contingency planning can directly affect China IIT study feasibility and timelines.

Particular attention should be given to local partner capabilities, import readiness, and for advanced therapies, the impact of patient-specific requirements on shipment and treatment timing. Leading practices include:

## Plan Early and Cross-Functionally

Align Clinical, Regulatory, Quality, and Supply Chain/Logistics teams at the outset of China IIT planning. Define roles, responsibilities, dependencies, and decision points across the sponsor, CRO, hospital/site, customs broker, and logistics provider to identify gaps early and avoid downstream delays.

## Treat China Importation as a Critical Path Activity

Develop the import strategy in parallel with clinical study planning and confirm requirements well before IMP shipment. This includes product classification, documentation, labeling, consignee and Importer of Record responsibilities, and customs clearance requirements. Incorporate realistic import and clearance timelines into the overall study plan.

## Qualify Local Partners for IIT-Specific Capabilities

Realizing the speed and cost advantages of China IITs requires sponsors to address supply chain, importation, and logistics considerations early and integrate them into the broader clinical execution strategy. Importation should not be treated as a downstream activity; decisions regarding import pathways, local partner roles, documentation, product handling, and contingency planning can directly affect China IIT study feasibility and timelines.

## Establish Clear Importer of Record and Consignee Responsibilities

Determine early which entity is able and willing to perform required import and consignee functions. Hospitals/sites may be reluctant to assume these responsibilities because of licensing, tax, liability, systems, or import capability concerns, making early alignment essential to avoiding late changes to the import model.

## Use Established and Fit-For-Purpose China Import Pathways

Evaluate ports of entry, customs clearance routes, local warehousing, and Free Trade Zone (FTZ) strategies based on the investigational material and study requirements. Where appropriate, consider established gateways/ports of entry such as Shanghai or Beijing and confirm that the selected pathway can support required cold chain or advanced therapy handling.

## Strengthen Documentation, Traceability, and Shipment Readiness

Ensure consistency across customs documentation, product information, clinical protocols, labeling, chain of custody, temperature control records, and declared clinical use. Conduct a coordinated pre-shipment review to identify gaps or inconsistencies before material departs the country of origin.

## Build Contingency Plans for CGT Logistics

For cell and gene therapies and other time- or temperature-sensitive products, plan for customs delays, patient-specific import requirements, temperature excursions, shipment disruptions, and treatment schedule changes. Where importation timing is tied to patient consent or treatment scheduling, map shipment and customs clearance activities directly against the clinical schedule.

## Monitor Evolving Regulatory and Customs Expectations

Maintain active communication with China-based regulatory, customs, and logistics experts throughout study planning and execution. Assess evolving requirements for potential impacts on documentation, import strategy, shipment timing, and overall study execution.

# Final Perspective

China IITs can provide substantial strategic value for sponsors seeking accelerated development timelines for advanced therapies, earlier clinical insight, and more efficient generation of proof-of-concept data.

However, realizing these benefits requires a level of operational coordination, regulatory preparation, and logistics and supply chain planning that many sponsors may initially underestimate.

Success depends on treating China IIT execution as an integrated clinical, regulatory, and logistics and supply chain strategy rather than solely as a clinical opportunity. Sponsors that plan early, establish clear accountability across local and global stakeholders, and proactively address importation and logistics and supply chain requirements will be better positioned to preserve the speed and cost advantages of the China IIT model while minimizing execution risk and avoiding preventable delays.

To learn more about Dark Horse Consulting Group's clinical team capabilities, please reach out to: [bd@darkhorseconsultinggroup.com](mailto:bd@darkhorseconsultinggroup.com)



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