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Your Clinical Supply Solutions

White Paper

Import/Export and Clinical Trial Supply

A steady and reliable supply of medicines is critical to a clinical trial's success.

Created by
Dan Pritchard

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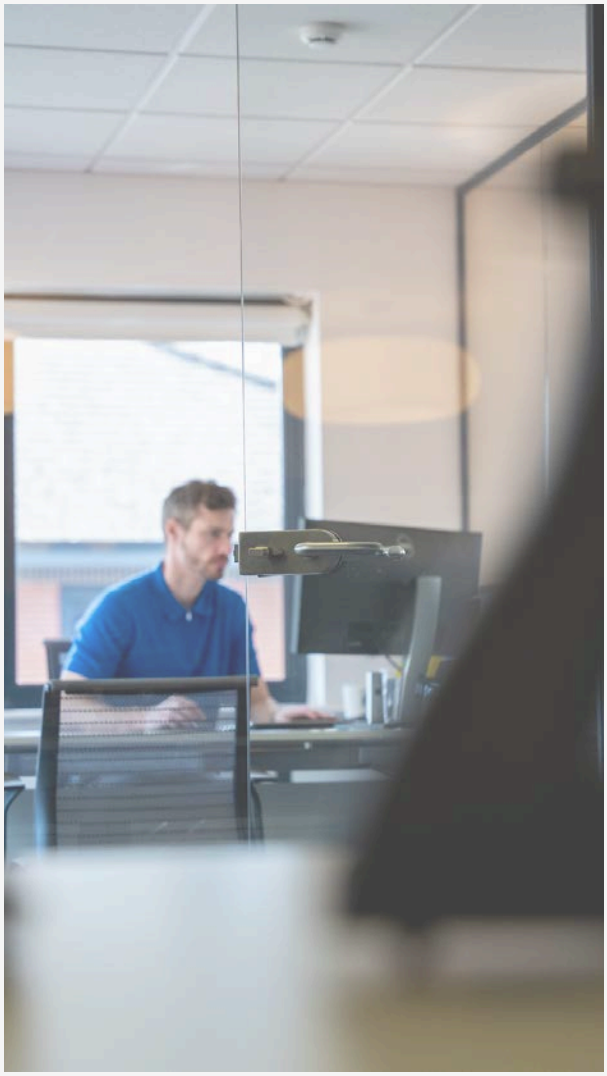
As trials become increasingly global, cross-border supply chains are more common place. Sponsors and procurement managers must ask themselves: "Will importing supplies be necessary, and how should I prepare?"

To those not directly involved in the processes, the topic of import and export might be daunting. This paper will explore the benefits and challenges of importing clinical trial supplies, offer advice on how to mitigate risks and provide guidance on how to successfully prepare to ship medications internationally.

Why might I need to import my clinical trial supplies?

Considering the use of supplies from international markets reduces reliance on the domestic market and provides much wider access to medications.
If your protocol allows the use of non-domestic drug, then you will have more options for supply at your disposal and a more robust clinical supply chain.
Overreliance on a single source creates vulnerabilities, especially if hit with disruptions outside of your control.



The prices of some medications vary significantly across markets. Opting to source the same or equivalent products abroad might provide access to more competitive prices, which, given the scale of some trials, could lead to a considerable reduction in overall costs. To be effective, the savings should dwarf the increased logistics costs and administrative burden.

If a trial spans multiple countries, a central stockpile of supplies also protects against disruption and offers uniformity and consistency of supplies across all sites in all countries. Utilizing and mastering importation processes unlocks a range of benefits and bolsters a clinical trial's supply chain.

What are some things I should be aware of?

Importation introduces complexities that sponsors and procurement managers must carefully navigate. Regulatory hurdles, logistical challenges, and hidden or misunderstood charges can all impact operations.

All import and export require customs brokers who file and submit the correct paperwork to the authorities to allow the smooth movement of goods across borders. This procedure carries a cost and it's important that the information filed is accurate and verifiable.

If you do not have access to a customs broker, specialist pharmaceutical couriers usually have dedicated customs brokerage operations, with straightforward set-up processes.

The Importer of Record (IOR) is a common term which refers to the company legally responsible for an import into a country. A sponsor can act as IOR, but Contract Manufacturing Organization's (CROs) offer IOR agreements that make them responsible for these aspects. These arrangements might be costly but are very convenient.

Importing can trigger duty and tax payments for the IOR. It's important to be aware of how these apply and that brokers and finance teams process them correctly.
Many charges can be deferred, recovered or simply waived if you can demonstrate exemptions. HS Codes (Harmonized System Codes) formally classify products and determine whether duty is payable. Clinical Trial Materials and medicines are generally exempt, but there are exceptions, so accurate classification is vital.

On top of general import rules, each country has its own regulations governing the importation of medicinal products. Non-compliance or missing documentation can result in delays or even shipment rejections. In the USA, there are multiple agencies that need to see and approve paperwork before goods can be released.
For example, you need to present additional documentation to The USDA and FDA at the least. Certain countries might also require an import license or equivalent permit, so seek advice from your vendor and customs agencies. Additional documentation requirements could be triggered by the presence of certain excipients, such as gelatine or other animal-derived substances.

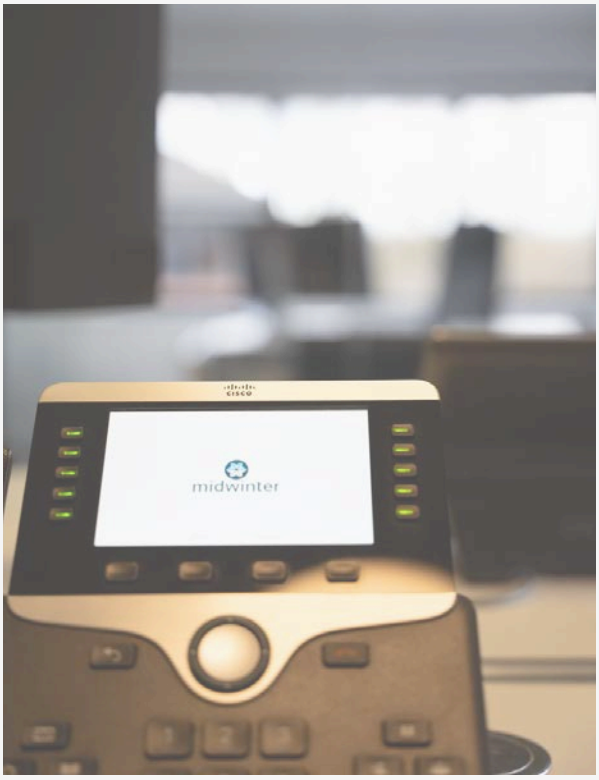
Failing to prepare is preparing to fail.

Successful imports require proactive planning and partnerships with dedicated service providers. Favourable outcomes are the result of multiple teams of people working together who can be relied on in their own specialist areas. With the right planning and advice, sponsors can effectively mitigate the risks and move products across borders with confidence.
As an importer, make sure you understand and agree the incoterms assigned to a shipment. Incoterms are standardized trade terms that define the responsibilities of buyers and sellers in international transactions. Who is responsible for clearing the goods at customs, paying import taxes, and insuring the goods? These are all important questions and incoterms can be adjusted and agreed on before a transaction takes place.

Sponsors should engage early with regulatory and customs experts, as early as the planning stages of a clinical trial. Import licensing or labelling requirements for each region should be identified and accounted for. Effective planning in the early stages can broaden a sponsor's options further down the line, and eliminate the need for last-minute adjustments.
Additional importation steps might be required which are specific to the country or territory, such as QP oversight in the EU. It is important that time is factored in for these unavoidable responsibilities. Being realistic about the timeline of events is key, and awareness of the hurdles and how long they take to jump will make your planning worthwhile.

Some medicines have strict storage conditions, which adds another layer of complexity if faced with delays. Specialist clinical trial logistics providers understand the importance of on time delivery and offer a plethora of additional services.

Do you know if your goods can be moved to a temperature-controlled warehouse in case of customs delay, and that the courier can physically access the goods at any time? You may consider employing the use of more sophisticated temperature monitoring devices, which provide GPS tracking and live access to temperature conditions.



Before dispatch, all shipping documents should be pre-approved with the IOR and customs agent, do not dispatch until signed copies of all necessary documents are in hand. To avoid hold-ups, it's important that documents are letter-perfect.

Summary

Behind every successful import of clinical trial material is significant work and collaboration between multiple stake holders.

You don't need to master every aspect of importation yourself if you outsource to competent vendors.
Importation might increase the logistics costs and complexity of clinical trial supply, but it allows access to lower-cost medicines from a larger market and can reduce the likelihood of supply chain disruption in the longer term.
While there are risks, they can all be managed with proper planning and the right vendor partnerships. These factors underpin a successful importation strategy most.
Do not be afraid to utilise the knowledge and experience of the relevant subject matter experts.
Hopefully, this paper provides an insight behind the scenes of import and export and identifies key considerations for those who are faced with import as part of their operations.

I'd love to hear from you with questions or thoughts at dan.pritchard@midwinter-solutions.com.

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