Ensure a timely arrival

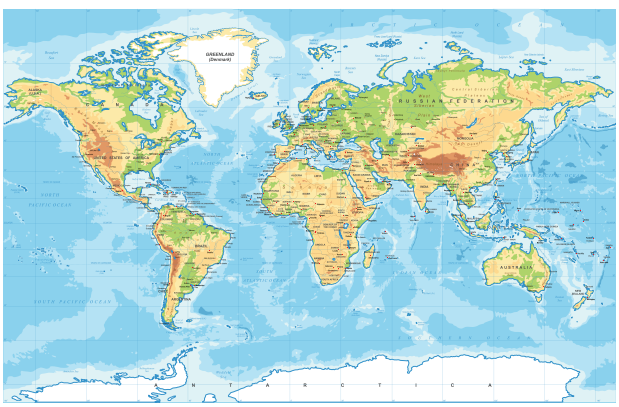
Stalled deliveries of clinical supplies to global investigator sites have the potential to derail trials and put study patients at risk. *Clinical Trial Insight* talks to Ian Hunter, commercial director of logistics at **Fisher Clinical Services**, about the company's strategy for minimising delays to ensure clinical supplies reach the sites and patients who need them on time.

How do you decide which couriers and shippers are best suited to deliver clinical supplies to investigator sites across the globe?

Ian Hunter: Our decisions about which couriers and shippers to use are based upon performance data and real-life experience. We ask couriers to provide several years of data to demonstrate, among other things, their rates of on-time delivery and the number of temperature excursions they've had. We also look at exception reports from our own experience with 500,000 shipments each year, request case studies and ask couriers under consideration to explain how they remedy situations if something goes wrong. We compare the data and experiences to determine which couriers reliably deliver clinical supplies in specific countries or regions. This total transportation management service enables us to select the best courier for our needs.

There's an assumption that selecting a premium courier – which typically costs five to ten times more than an integrated courier – yields better service, but that isn't borne out by data. Data shows that the type of courier doesn't make a difference; in some parts of the world, an integrated courier will actually give you superior service. Some couriers are simply better than others at going into certain countries or regions.

Consider, for example, that you need to ship supplies into a challenging country, such as Argentina, Brazil, China, Russia or Ukraine. Based on performance data, you learn that a premium courier is on time 98% of the time, versus an integrated courier that is on time 95% of the time. If the product you're shipping is a non-biological and readily available at low cost, you might be willing to accept a 95% rate of on-time delivery for significant savings. If, however, the product is a biological or in short supply, you might opt for the premium carrier. The data enables you to make informed decisions.



FIsher Clinical Services has facilities all over the world.

Can you explain how you remain up-to-date on changes in import requirements and incorporate those considerations in your planning to maximise timely delivery?

We maintain a comprehensive database that is continuously updated about import requirements in all 120 countries to which we ship clinical supplies. The information in the database comes from knowledgeable customs brokers in these markets, who are typically the first to learn about such changes. Customs brokers act as professional agents for importers, preparing and submitting all documents required for clearing goods through customs.

When import requirements change, as they frequently do in countries such as China, the local Fisher Clinical Services organisation talks to the broker in order to update operations immediately. This is critical because you don't want to have a shipment arrive and then learn that import requirements have changed, that customs officials want something you don't have, such as a different kind of declaration or tax agreement. Should that happen, the shipment will sit in customs until someone on the ground resolves the problem.

One of the advantages of owning facilities around the world, as we do, is that we have people on the ground that are in constant communication with our customs brokers. In countries that have a 'green light' system, our local employees provide the broker with the paperwork necessary to clear a shipment in advance of its arrival. This requires considerable preplanning, but it pays off because shipments pass through customs with no hitches.

Would you compare the use of air, sea and land in shipping clinical supplies to different regions to ensure the best value for the money?

More often than not, couriers use multimode transport. The key determinants are connection speed and cost management. And, as you can imagine, the faster you need something delivered, the higher the cost will be.

All of our international express couriers use a combination of air and road for the fastest turnaround time possible. This includes everything from small vans to trailers and passenger/cargo aircraft. Those who own an airline, such as FedEx and DHL, optimise those aircraft.

One difference between premium and integrated couriers is use of aircraft. A premium courier will use a direct commercial flight to get the earliest lift-off time, whereas an integrator will use their hub-and-spoke network. If inventory is plentiful and inexpensive and the sites can be stocked up, a slower service using minimal air travel is optimal from a cost point of view.

Multimode transport is used even in domestic markets, since we frequently need to reach remote areas many miles away from the nearest airport and a road parcel service would take too long. Sea is rarely used in clinical trial work. Final costs are difficult to pin down due to the number of agencies involved and delivery time can be as long as eight weeks. When sea is used, it's for bulk stock of shippers or other bulky, less critical items. Also, many clinical trial depots are small and find it challenging to manage a container full of goods.

Can you describe your strategy for minimising hold-ups and avoiding delays that can arise from regulatory inspections when importing/exporting trial supplies?

Our strategy is one of effective communication, flawless documentation and on-the-ground expertise. We're in constant communication with customs officials. We tell them what we're shipping and when it will arrive. We show them the shipper, so they know exactly what they can expect to see. We explain that the materials will be used in clinical trials and that there are people in their country waiting for the materials we're shipping. People are people and they relate to the necessity of what we do.

Another critical element is documentation. Paperwork is almost always the reason why materials are held up in customs, so we make sure ours is complete and correct. Customs inspections and regulatory interventions typically occur when paperwork, such as valuation, appears incorrect. Importers who misdeclare the value of a shipment find that every shipment from that point on is subject to inspection. Reputation counts for a lot with customs officials. It's about whom they feel they can trust. I'm proud of the fact that we've had no hold-ups or regulatory inspections for more than two years in China, because we have the right paperwork and we talk to the customs officials before we ship. It works very well. Finally, we use only customs brokers who are experienced in clinical trials.

Would you evaluate the advantages and disadvantages of manufacturing in one or multiple countries from an import/export perspective to determine the best strategy?

A key part of our strategy involves the use of free trade zones (FTZs), which confer significant economic advantages. For example, manufacturing and packaging supplies in FTZs confer tax and duty-free status for studies taking place outside these countries.

Fisher Clinical Services owns and operates two FTZ facilities in strategic locations – Suzhou, China, and Ahmedabad, India. These facilities are subject to fewer requirements and regulations than facilities that might be located in Beijing or New Delhi, for example. In addition to being duty-free enclaves, no import licences are required, nor are there any routine examinations made by customs officials on import or export shipments.

Effective communication and correct documentation ensure that Fisher Clinical Services' supplies are rarely held up at the customs stage.

These days, the challenge is the higher volume of smaller trials, and that's why we built the FTZ facilities. The Suzhou facility supports trials taking place in Asia. It's easier, faster and more economical to do that from Suzhou than from the US or Europe. The Ahmedabad facility supports the domestic Indian market, which produces and exports many generic drugs.

In considering where to build infrastructure, it's important to keep in mind that countries where trials take place may change. Ukraine may be a hot location today, but the same volume of studies may not be taking place there in two years. Sponsors could decide that they can access a better patient population in Kazakhstan, for example. That mitigates against having infrastructure all over the world. You have to centralise to some degree.

With respect to centralisation, it's worth noting that it's more efficient to manufacture and label in one location than to manufacture and label in multiple countries. The choice is clear when you consider that time is the currency of the global biopharmaceutical industry.

How would you summarise your overall strategy for on-time delivery?

Our strategy has evolved from our experience with half a million shipments a year. That experience has taught us to rely upon real-life performance data, manage evolving regulatory or other changes instantly, and have knowledgeable partners on the ground, including the local employees at our facilities around the world. We also establish the shortest possible supply chain – the longer the supply chain, the greater the risk of failure. It's just common sense. ■

Further information
Fisher Clinical Services
www.fisherclinicalservices.com