A World of Opportunities
Your focused field guide for specialty transport to emerging markets

ISSUE 1 | SEPTEMBER 2014
Map to the guide

- Are there any markets left to emerge? 5
- Lining up for latin america 10
- China: expansive opportunities, extensive requirements 14
- Singapore: investing the future of life sciences 16
- Turkey: at the crossroads of asia and europe 18

Foreword

What documentation and steps are required to clear a product shipment for entry into China? What is the ability for major airports in Brazil to store refrigerated products while they are awaiting customs clearance?

When it comes to specialty logistics, the world may be growing smaller—but that does not mean it is any less complex. Pharmaceutical manufacturers conduct clinical trials globally in an effort to reach new populations and gain greater cost efficiencies. But many of these advantages can be diminished—or wiped away entirely—if the transportation of products, supplies and samples is disrupted. World Courier has prepared this field guide to give our partners insight into the processes, requirements and challenges of shipping to a handful of the 190+ countries we service. Together, we can drive toward success in these new and emerging markets.
When it comes to clinical research, an already small world continues to grow even smaller. In no area is this more evident than site selection for clinical trials.

North America, Western Europe and—to a lesser extent—Australasia once served as prime locations for the majority of research. But these Western markets are approaching saturation, which has led to a lack of naive patients who are available and willing to take part in trials.

Companies have thus turned to new global locations to run trials—an effort made far easier due to the huge improvements that emerging markets have made in investigator and patient identification, as well as regulatory initiatives. In fact, some say that all feasible emerging markets have already emerged, and that there are no other new markets where entry makes sense.

India and Brazil serve as prime examples of rapidly evolving markets for clinical research. Both countries have seen significant investment in infrastructure programs to improve the way they handle clinical trial applications—including trial review—and the granting of import licenses and permits. IMP supplies can be imported relatively quickly to allow trials to occur concurrently with those in Western Europe and North America.

Other global regions have seen a similar rise in attractiveness as clinical sites. Companies have realized significant cost reductions by performing trials in Eastern Europe, Latin America and Asia. In Russia and China, for example, it’s possible to reduce operational costs by conducting trials in large hospitals, which have patient catchment areas that number in the millions and can speed patient recruitment.

National regulations have also spurred on the increase in the geographic disbursement of clinical trials. Many countries now require trials to be conducted within their borders prior to the drugs’ introduction in those countries. China spent approximately 66.8 USD billion on pharmaceuticals in 2011—so local trials within that country are vital to any global pharmaceutical company’s long-term growth and success.

“Some say that all feasible emerging markets have already emerged, and that there are no other new markets where entry makes sense.”

1 International Federation of Pharmaceutical Manufacturers & Associations
Non-traditional Sites Seeing Growth
Apart from the large—and somewhat obvious—global markets, smaller countries are experiencing their own boom as trial sites.

For example in South America there are almost 6,000 trials. In Africa, there are over 4,000. In Southeast Asia, there are over 3,500. And while these markets appear to have truly emerged, it’s important to understand that not every individual country has emerged to the same extent.

South Africa might have around 1,900 trials, but Brunei Darussalam has only one carcinoma study running. Libya has but four completed studies and is actively recruiting for a fifth. Many of the countries with small numbers of studies have been held back by political or civil unrest, and even United Nations sanctions for all but humanitarian aid.

Other countries appear primed for growth, if given enough time. Specifically, the Middle East and Africa are showing significant growth in clinical trials numbers as the industry looks for even more new destinations, and not just in South Africa.

Clinical Logistics: Always Uniquely Challenging
For clinical trial logistics, does it even matter how far down the route of emergence each country is?

Every country represents challenges in logistics: Ensuring temperature control, arranging customs clearance and regulatory release. Every country is also different. Every shipment can be different. There are times when shipping into North America and getting shipments through FDA and USDA requirements presents more issues than sending to Sub-Saharan Africa.

With so many obstacles in arranging shipping—many of which require knowledge of local practices, from how to address the package to what storage options are available in individual airports—one could argue that being first to enter a market offers a distinct disadvantage. First entrants must forge ahead into a country to find out about customs requirements, regulatory requirements and the practicalities of the supply chain. More than likely, first entrants must train local staff in all the necessary aspects of clinical trials and potentially introduce the whole culture of clinical trials to the local infrastructure.

Consider a few examples of frequent challenges that accompany specific markets in Southeast Asia. Vietnam is the easternmost country in the Indo-Chinese peninsula. The population is approximately 90 million, and there are 65 open clinical studies. Sending in without doing ample homework is a recipe for disaster. Shipments to Vietnam cannot come addressed to an individual, as it would be considered a personal package (even for a pallet-sized package). The recipient would likely become personally liable for any duty or taxes applied to the shipment. This can lead to problems making deliveries into a big hospital, particularly for time/temperature sensitive items. Clinical trial supplies received into a pharmacy department are also at risk of being stored incorrectly, because personnel with knowledge about the specific storage requirements may not have been advised.

In Cambodia, at Phnom Penh International Airport, there is no freezer and only one refrigerator set at +2 to +8°C: (interior space: 4x3x2m; door size: 1.8x1m), which is not qualified or controlled. There is a “controlled ambient” area set at +20 to +25°C: which is also not qualified or truly controlled, despite the name.

"China spent approximately 66.8 USD billion on pharmaceuticals in 2011—so local trials within that country are vital to any global pharmaceutical company’s long-term growth and success."
Customs clearance can take many days, depending on the number of clinical trial shipments arriving at any one time, type of supply and country regulations. During this time it may be possible to access the consignment to refresh refrigerant, but knowledge of all these facts is crucial to shipment success. The right information makes it possible to plan and make selections about the airport of entry, packaging and even the time of year to ship.

Laos serves as another prime example where local knowledge plays an essential role in logistics. The country (26 studies) has three seasons in the year: hot, cold and rainy (although the temperature is rarely below 15°C even in the cooler months). August and September see a significant rise in rainfall, with frequent tropical downpours. Given the limited airport facilities and the significant time that shipments can be left on the runway, wise companies send shipments a couple of weeks early or later to avoid the risk of weather damage.

All this knowledge comes as a byproduct from companies that were brave enough to be first entrants into these countries, companies who were able to establish and encourage the available infrastructure to produce a friendlier environment for future clinical trials.

Does it matter whether a country has emerged? For a company’s financial standing and positioning in the global marketplace, it absolutely matters. For logistics and study set-up, it matters much less, as every country along the spectrum will have special needs. The greatest tools in our arsenal are healthy amounts of patience and persistence.

With these tools, the industry has taken the antiquarian globe and crossed off “Here be Dragons” around the world, as we go together into previously uncharted territories.

“Vietnam is the easternmost country in the Indo-Chinese peninsula. The population is approximately 90 million, and there are 65 open clinical studies. Sending in without doing ample homework is a recipe for disaster.”
Lining up for Latin America

Conducting trials in Latin America offers tremendous value—but it can’t be realized without specific, local knowledge

With worldwide attention placed on Brazil for this year’s World Cup—as well as for the 2016 Olympics in Rio de Janeiro—Latin America has taken center stage in the sporting world. But it’s not only in sports that Latin America has come to prominence. Clinical trials have also experienced a boom throughout the region, with more trials occurring in more locations than ever before. Global pharmaceutical companies have set up more than 5,900 trials in the region. More than 2,100 have occurred in Mexico, alone. A quick look clearly shows why pharmaceutical manufacturers have shifted focus and funds toward R&D in this market:

- **Large total population:** More than 570 million people call Latin America home, with the majority of them in Brazil (192 million) and Mexico (103 million). Add in Argentina (41 million), and the total population surpasses that of the United States. Working through only three, federal regulatory bodies to reach such a vast population—and at a substantially reduced cost for operations—presents a significant advantage when setting up clinical trials. Despite the presumably bright future for clinical research in Latin America, challenges still abound for manufacturers working in this market.

- **Population density:** Dense urban areas provide another avenue to gain cost efficiencies for manufacturers who seek to reach a large volume of trial subjects without having to spread their operations too thin. At greater than 22 million residents, Mexico City is one of the largest metropolitan areas in the world. Sao Paulo is not far behind, with 20 million, and Buenos Aires and Rio de Janeiro both top 10 million each.

- **Variety of data:** With so many people in the region and such a variety of healthcare systems and economic conditions, manufacturers conducting trials in Latin America are bound to gather a wide spectrum data sets—vital to successful studies.

That said, it’s important to remember that Latin America includes 20 individual countries, each with its own regulatory requirements intended to serve its own, vastly diverse populations. Even something as foundational as language becomes more complex as one digs deeper. Most people in the region speak either Spanish (around 340 million) or Portuguese (around 192 million). But the region also includes large pockets of native French and Creole speakers. In Patagonia, the Welsh-speaking population is thought to be larger than the number of native speakers in Wales.

Conducting trials in the region, then, becomes an exercise in seeing the vast opportunities in the region as a whole—while also accepting and understanding the nuances of individual markets. For example, in some countries (such as Argentina), all materials have to be submitted at the moment of the initial regulatory submission, while in others, they may not be needed until the protocol is approved and the import license is requested. As a result, it can become extremely difficult to estimate timing and costs in the early stages of planning a project.

**Why Latin America?**

**Why the market is ripe for R&D.**

**Population of 570 million+ with the majority in Brazil and Mexico**

- Dense urban areas like Mexico City offer cost efficiencies
- The spectrum of healthcare systems and economic conditions offers vast data sets

**Mexican Adventure**

The Mexican Ministry of Health (COFEPRIS) has experienced delays recently due to the increased volume of clinical trial applications. Where before, the agency had regularly met its target of three months, this can now be up to four or five months. The good news: a previous system called “negative ficta” (which meant that companies should assume an unsuccessful trial application if COFEPRIS had not confirmed approval within the three month timeline) is no longer applied, due to the longer approval process.

Importing requires care and a host of documents. Products with a high value originating from a country with international trade agreements with Mexico (including the United States and Canada) will pay less duty, providing a Certificate of Origin is available together with the import permit.

Due to complicated rules, an import permit is not always required. For clinical supplies and medical kits, customs rule 3.1.28 (formerly rule 3.1.11 and rule 4.3) allows the import of drugs, kits and clinical supplies for clinical trials without a permit if the protocol is approved by COFEPRIS. Kits may be imported under rule 3.1.28 without a permit. In all cases, it remains prudent to verify any shipment strategy with a qualified logistics provider.

In most cases, companies will need to import with an import permit, which should be obtained from COFEPRIS by the importer of record, takes 30-60 days and expires after 180 days. This permit is valid for a specific quantity, and requires the importer of record to also apply for the import license, which should be obtained from the Ministry of Health (COFEPRIS) and requires the importer of record to also apply for it.

**The Mexican Ministry of Health (COFEPRIS) has experienced delays recently due to the increased volume of clinical trial applications.”**
sanitary registration, which takes 20–40 days. Every shipment must be accompanied by a commercial invoice, which must show unit value, quantity and total value. Everything has to match the import permit, and shippers should take particular care over the details. Any small issue will result in significant delays.

If the value of any shipment exceeds 1000 USD and/or it requires a special license—which is advised when the protocol approval is issued—then it must be cleared as a formal entry, needing a broker. All brokers pre-inspect (open) shipments before declaring them to customs, as the customs authorities have the right to open all shipments to ensure that products match with all documents (invoice, import permit and origin certificate, if applicable). If customs authorities find that the product does not match with the documents, then all stakeholders including the importer of record and the broker can be fined, and an embargo applied.

**Brazilian Salsa**

As part of the vaunted BRIC countries (Brazil, Russia, India, China), Brazil has spearheaded the drive to bring clinical trials to South America. Brazil’s regulatory agency ANVISA is aiming for a trial approval time of 45 days, but to-date they have failed to achieve this demanding timeline and it often takes months for approval to be granted.

When it comes to shipping, every single shipment requires an import license, applied for by the importer of record and typically taking around a week. ANVISA demands that consignees are registered in the agency’s electronic control, which is arranged for by the importer of record. All shipments need the full litany of customs paperwork: invoices, permits and an electronic paper (GVS), which is unique to Brazil. This GVS process requires fees to be paid on a sliding scale before shipments can be cleared through customs—free for public institutions, 15-30 USD for private corporations. Consignees can give powers to apply for the GVS to their transport company, which are also more likely to expedite the process.

**Argentine Tango**

Argentina has proved an increasingly popular location, and the country has invested heavily in clinical trials. The regulatory agency ANMAT (National Administration of Drugs, Foods and Medical Devices) was created in 1992. It aims to work to a three-month approval timetable and introduced an electronic management system to work toward this. As with Mexico and Brazil, this stated goal is not always followed. Even when an approval is granted, it can still take two months for ANMAT to issue the import permit to allow any supplies to be brought in.

Apart from this permit—which is issued for the whole study—another permit is required for every shipment in the protocol, and this takes a full working day to obtain. ANMAT charges a fee for each import/export permit related to pharmaceutical shipment/drugs. At time of this writing, the fee is 239 USD per import permit and 105 USD per export permit.

February 2012 marked the introduction of a new import regulation, 3252/12, applicable to formal import clearance via cargo section. In this instance, the importer of record must declare details on Argentina’s customs website before a purchase order or similar document is issued. This process is known as an “affidavit of anticipated importation (DJAI).” Finally the customs invoice must be submitted with another form to customs for each particular import. This form must also include departure and arrival date of the shipment. Customs entries can only be made after proper and timely registration of all the documents above.

This complicated process, which is mirrored in many Latin American countries, means that many companies use an external broker to clear their shipments, which can make the clearance process run glacially slow. In the meantime, shipments must be kept at the right temperature for the duration of their journey. Each airport has differing facilities, and it is vital to be sure about what is available.

While the delays in issuing approvals and permits can be frustrating, the longer approval processes give companies the chance to plan thoroughly for shipping—avoiding the anxiety and costs of having shipments held at customs for any longer than necessary. Local knowledge is vital for success, and finding partners who understand the intricacies of specific geographies and cultures is an often-overlooked component of a successful clinical trial.

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**Example: Argentina**

**Temperature control area**

**IMPORTS**

- **Total surface:** 1030m²
- **Freezer:** -18°C
- **Refrigerated area:** +2°C to +8°C
- **Controlled ambient:** stated range of +15°C to +17°C.

**EXPORTS**

- **Total surface:** 4310m²
- **Freezer:** -12°C
- **Refrigerated area:** +2°C to +8°C
- **Controlled ambient:** +15°C to +17°C.
China: Expansive opportunities, extensive requirements

China is a land of superlatives: the world’s second largest country by land area, with the largest population at 1.35 billion and growing. It is incredibly diverse, with 56 recognized, distinct ethnic groups. Mountain ranges form a natural border to the West; the Gobi and Taklamakan deserts are in the North and there are subtropical forests in the South. It has the Yangtze and Yellow Rivers, the third- and sixth-longest in the world.

More important for the global healthcare market, it has the world’s second-largest economy by both nominal total GDP and purchasing power parity. It is the world’s largest exporter and importer of goods. China spent approximately 66.8 billion USD in 2011 on pharmaceuticals alone.

China is not unique in requiring that any drug sold must have been tested in a clinical trial conducted in China. Pharmaceutical companies have little choice if they wish to market their drug once it is approved. Given that China makes up 19 percent of the world’s population, and is expected to overtake the United States as the world’s largest market by 2020, there is no wonder that it is right at the top of the list of target countries. Currently, more than 5,200 trials are taking place there. At one point, the perception existed that it could take a couple of years to receive approval to run a trial, but timelines have reduced dramatically. China is working toward a 90-day process, and typically it takes between three and six months. China benefits from a centralized healthcare system, and with such a huge population and regional centers of excellence, there is a large patient pool accessible very quickly for many disease states in China. Recruitment can be swiftly completed.

When shipping takes place, probably the most important single document is the import permit issued by the BFDA (Beijing Food & Drug Administration). There are a number of documents to be brought together in advance, which must be supplied to the BFDA for the import permit to be issued.

Once the permit is in place, arrangements should be made to import through Beijing rather than another port, in order to comply with all national requirements. The documents required include a customs invoice, a copy of the draft airline paperwork (the MAWB), packing list, certificate of analysis, clinical trial approval, which comes from the consignee, together with a copy of the shipper’s business license and a first leg document showing the batch/lot number as indicated on the invoice. The customs invoice is very detailed, including the shipper’s and consignee’s name and address, what the contents are, shipment commodity description, country of origin, expiry date, batch number, manufacturer company name, and shipper company name—all of which need to be confirmed with the importer of record, and every single one of which must match the details on the inner packaging label on the packages. Any discrepancies lead to delays at customs and China Inspection and Quarantine.

Every shipment must be sent with a packing list, and this is another place where attention to detail is imperative. The packing list must include specifics on the content and the number of pieces, net weight and gross weight. Once the packaging has been decided, it’s very difficult to make changes. Customs officials are expecting these exact details, and if anything is different when it arrives, they won’t let the shipment go through without further inspection. This may lead them to require a new import permit, during which time the clock is ticking, the shipment waits at the airport and the potential grows for it to be moved into storage at the wrong temperature—or even damaged.

In Beijing, it takes around two days to clear customs, or longer if the shipment is selected for inspection. Storage facilities at the airport need to be booked in advance, and documentation is required for temperature-controlled storage. Temperature-controlled shipments selected for customs inspection will be taken out of the temperature-controlled area into an uncontrolled ambient area until inspection, which takes 24-48 hours. Packing the shipment carefully so it can withstand this temperature challenge—which could be several days after leaving the origination point—will almost certainly need a box using phase-change materials to control temperature. The consignee also needs to provide letters of instruction for customs purposes and quarantine purposes, its 10-digit registration code for both customs and CIQ and an authorization letter for the transport company to collect from the airline. It is clear that China can be challenging, but systematic processes lead to success, a minimum of delays and ultimately access into this vast marketplace.

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Singapore: Investing in the future of life sciences

The country’s approach has been to heavily invest in order to make Singapore an international hub for trials and research. It boasts seven research institutes and five research consortia in a country with a population of just 5.3 million, around the same size as the Washington, D.C. metropolitan area. Many companies have invested in Singapore to build their storage and distribution centers, using the most up to date supply models to allow just in time deliveries of clinical trials supplies to take place to investigator sites.

Shipping into Singapore

If materials are ultimately delivered within Singapore then they must be completely cleared and subjected to 7 percent GST tax. They are exempt from duty. Shipment may be tax-free if the importer is registered with the tax department for tax exemption status. A license may be required when shipping certain types of biological samples for testing into Singapore. Drugs for local use require the relevant license, applied for by the CRO, which takes about 4-8 weeks to be issued. The importer of record must apply for an import license, which is a controlled document. In addition to this all importers must be registered with Singapore Customs in order for the Customs Permit to be applied for by the local depot. It is normally immediately approved. Items undergo a limited clearance, but must be re-exported from Singapore within a period of two years. This allows companies to ship bulk trial drugs into the depot for prompt dispatch to clinical trial site.

Regulatory & Facility Considerations

The Health Sciences Authority works within PIC/S (pharmaceutical inspection co-operation scheme), an international body, for the appropriate standards of GMP and GDP and it operates a voluntary certification scheme for interested companies to seek official certification. A GDP certificate is issued when the company’s quality system has been audited and found to comply with any of these standards. All companies importing material into Singapore should conform to the PIC/S GMP and GDP standards. Practical information and guidance is available on the HSA’s website.

Importation requirements have been simplified for supplies when they are being sent to a storage location in Singapore, to then be forwarded into other parts of Asia Pacific. They are subjected to a redistribution license, which must be applied for by the local depot. It is normally immediately approved. Items undergo a limited clearance, but must be re-exported from Singapore within a period of two years. This allows companies to ship bulk trial drugs into the depot for prompt dispatch to clinical trial site.

Singapore Changi Airport has a perishables handling center, situated within the free trade zone, with areas available ranging from -28°C through 2-8°C to +18°C. This is located at Airfreight Terminal 2. The facility allows for shipments to be accessed to replenish refrigerant (add ice, change gel packs, change batteries, etc.) while still under customs control, and when under the control of the airline authority. This allows for the maximum flexibility in controlling temperature whilst undergoing clearance.

Singapore chose to invest heavily in the infrastructure needed to smooth the transit of pharmaceuticals including clinical trial supplies. Its decision to do so is now reaping the rewards with all the significant players in the market setting up facilities, bringing knowledge, trade and international investment into the region.

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1 www.clinicaltrials.gov
3 www.clinicaltrials.gov
Turkey: At the crossroads of Asia and Europe

To a lot of Europeans, Turkey is—let’s face it—tucked away past the Balkans, out on the eastern edge. It’s a great place to go on holiday, has lovely beaches and some interesting archaeology, and then there’s that song about Istanbul (not Constantinople) that remains a pop culture fixture. But if that’s all that comes to mind when you think about Turkey, then you really are missing the point.

The country was a founding member of the UN and belongs to NATO, the OECD and the Council of Europe. It is one of the G20 economies, is an associate member of the EU and fully part of the EU Customs Union. The first application to join the EU as a full member was made in 1999 and ongoing negotiations started in 2005.

As a bridge between Europe and the Middle East and Asia Turkey occupies a unique position, with a population of around 75 million, nearly three quarters of whom live in towns and cities. Most are considered to be ethnically Turkish, but there are also people of Armenian, Greek and Jewish origins, with minority ethnic groupings of Abkhazians, Albanians, Arabs, Assyrians, Bosniaks, Circassians, Georgians, Hamshenis, Laz, Crimean Tatars, Bulgarians, Pomaks and Roma.

From a pharmaceutical R&D perspective, this wide diversity offers a great opportunity for data spread within a clinical trial—all while dealing with one administration, the Turkish Medicines and Medical Devices Agency (TMMDA). The Turkish regulations are completely in line with EC Directives (EC 2001/20 and EC 2005/28), so adding the country to a trial running within EU countries should not require significant additional work, following ethics approval.

To date, over 1,600 trials have taken place in Turkey. The Middle East and North Africa region as a whole accounts for only around 1 percent of the distribution of clinical trials, so this low density of trials offers significant opportunities for growth.

What Does the Trial Environment Look Like?

Turkey has a highly centralized healthcare system and many world-class healthcare facilities, following a significant reform programme introduced in 2003. In 2012, there were 128,772 physicians treating an average of 583 patients each. Doctors are interested in participating in clinical trials and speak good English. Turkey is considered to have a unique patient base especially for studies in hepatitis, and genetic diseases.

The Clinical Trials Department of the TMMDA reviews clinical trials in Turkey. Its staff numbers have grown exponentially in recent years. Under the Clinical Trials Department, there are a phase evaluation unit, bioequivalence/bioavailability evaluation unit and a post-marketing surveillance evaluation unit. The department has a programme working to standardize ethics approvals and improve on time from submission to approval. The goal is to reach targets of 30-day approvals for ethics and 30-day approvals for the Turkish Ministry of Health, which monitors the timing taken by ethics committees and has taken more of a performance-based approach.

To date, over 1,600 trials have taken place in Turkey. The Middle East and North Africa region as a whole accounts for only around 1 percent of the distribution of clinical trials, so this low density of trials offers significant opportunities for growth.

Figure 2. Numbers of clinical trials from 1997-2012

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2 Clinicaltrials.gov.
4 http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3878463/
5 http://www.tmda.gov.tr
Trying to pull together all the requirements for paperwork for a study application can be a challenge. The sponsor’s legal entity must deal with insurance, as well as contract and budget forms. Each ethics committee will have slightly different needs and diversified requirements depending on the nature of the sites/institutions (type of documents required, different format/forms, meeting schedules). The ethic committee at a site usually deals with every type of application, and a lack of specialisation can delay the application.

**Shipping into Turkey**

An import permit issued by the Turkish Ministry of Health is needed to send in supplies, and the consignee should always apply for the import permit before the arrival of the shipment, as it normally takes about a week for the permit to be issued. A copy of the invoice must be provided in the application. Permits are normally issued on a per shipment basis, but sometimes they can cover all the shipment in a given period for the same study and contents, same shipper and same consignee.

Access to the shipment is not always permitted during the clearance process, so adding dry ice or changing gel packs might not be an option. As a result, temperature-controlled shipments could be severely jeopardized by delays caused by permit issues. In some cases, an application can be made for a customs broker to receive access, but this cannot be relied upon.

**Invoice Requirements**

- ORIGINAL invoice required, signed and/or stamped with blue ink by shipper/exporter
- Zero value is not accepted
- Must be customs invoice or commercial invoice proforma not accepted
- Must show a unique invoice number
- Must show customs tariff Code(s)
- Non-compliance will result in serious clearance delays as customs may refuse any statement provided afterwards

Government institutions must use their own broker to clear shipments and are not allowed to give a power of attorney to another customs broker. They are then dependent on the speed at which the broker works and the number of other shipments under their control. Because of the Turkish customs regulations, importation can only be handled by a consignee appointed customs broker.

**Temperature-controlled Storage in Istanbul**

All airline handlers offer +2°C to +8°C and -20°C storage. Airlines do not provide temperature reading of their storage facilities. By experience, World Courier advises that temperatures have been fairly stable in the past. Please note that all perishables (food, biologics and pharmaceuticals) are stored in the same area. There is limited controlled ambient storage—and it is only available to certain airlines—so routing and airlines choice can become extremely important, depending on shipment requirements.

In its Vision 2023, Turkey has outlined a series of goals for the country to achieve by the 100th anniversary of the founding of the Republic of Turkey. The goals specifically recognize R&D investment in pharmaceuticals as a critical growth area and offers substantial incentives for sponsors. Turkey offers a stable platform and growth potential for clinical trials. Turkish investigators are well educated and connected to the clinical trials arena. The authorities are much more responsive and put in a concerted effort to attract more trials to Turkey. With all these factors in place, consensus opinion points to an increase in the number of trials in Turkey over the next 3-5 years. It’s no stretch to say that for clinical trials, it could indeed be a Turkish delight.