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Coordination

Supply chain

Optimizing clinical trial logistics for success

A comprehensive guide to ensuring the timely and secure delivery of clinical trial materials worldwide

Introduction

Supply chain logistics can make or break the success of a clinical trial. The importance of efficiency and ensuring that materials are delivered on time, at the right temperature, and without regulatory delays cannot be overstated.

This eBook describes how services that integrate various logistics elements—including transportation planning and management—can support optimized clinical trial outcomes. Small and large drug developers can benefit from collaborating with partners who provide this differentiated service offering as part of an end-to-end solution.

Thermo Fisher Scientific's Total Transportation Management (TTM) is a comprehensive and integrated approach to clinical trial logistics with a global reach.



The challenges of clinical trial logistics

The complexities associated with shipping clinical materials for trials may only be fully understood by those for whom logistics (complex regulatory requirements, logistical coordination, temperature control, inventory management, data integrity, and traceability) are a daily occupation. However, delays or missteps in any one of these logistics elements could affect nearly every stakeholder.

Clinical materials come with complex requirements. The best transportation and logistics solutions will not look the same from one project to another. But there are several types of challenges that are common—all of which are a threat to the project budget and timeline, the company's reputation, and/or the sponsor's ability to meet patient-centered goals. For example, depending on the phase and therapeutic area, the cost of delays in clinical trials can reach more than \$50,000 per day. These costs include storage fees, reshipping, and the impact on trial timelines [1]. Failures in cold chain logistics management alone result in an annual loss of approximately \$35 billion in revenue [2].

An integrated approach is essential to overcoming these challenges and should certainly include experts with country-specific understanding of regulatory and customs requirements who can communicate in the appropriate languages and with each other to ensure a seamless process with minimized risk. The advent of Brexit in the UK, with all its associated complexities, highlights the need for continuously updated understanding of the evolving commerce and import/export requirements across the globe. In addition to a robust network of in-country experts, a portfolio of strategically located facilities across the EMEA is critical to successful logistics management in clinical trials programs that have a global reach.





Thermo Fisher's Total Transportation Management (TTM)

Thermo Fisher's TTM is a global, integrated service that supports customers through its international network of qualified carriers and cold chain management, customs and regulatory guidance including value added tax (VAT) and Importer of Record (IOR) support, and continuous, real-time monitoring and proactive risk mitigation. All these logistics aspects are integrated into one seamless service guided by a network of experts with a goal of reducing stress and workload for the sponsor's study management teams.

TTM provides this level of service by offering several key features:

Courier selection and management

Based on the client's needs, TTM selects the most effective shipment mode and couriers from a vetted, global network including over 120 countries and direct-to-patient services for decentralized trials.

Customs and regulatory guidance and facilitation

To support customers with compliance, TTM offers IOR and Qualified Persons (QPs) services as well as a UK-based customs warehouse. IORs bridge the gap between complex international regulations and a sponsor's research goals by ensuring the imported goods comply with local laws (which can vary greatly by country), accurately filing duty entry and other related documentation, and paying the assessed import duties and other taxes as necessary. QPs play a crucial role in the supply chain by certifying each batch of medicinal product meets certain quality criteria. TTM offers expertise in the Brexit-related regulation changes that affect transport of materials between the EU and the UK. The UK-based customs warehouse is a unique offering that can bolster readiness around regulatory, tax, and trade issues by providing tax concessions, long-term storage, quality preservation, integrated logistics services, and stability in the supply chain.

Cold chain supplies management

An increasing number of drugs are sensitive to changes in temperature and failures in cold chain transportation can cost billions of dollars [3]. TTM tracks and monitors temperatures from the point of origin through to the distribution/investigator's site and offers controlled ambient, refrigerated, frozen, dry ice, and ultracold supply management. TTM will also recommend and facilitate optimized transportation and reverse logistics strategies.

Global quality management systems

TTM offers a comprehensive program under the oversight of Thermo Fisher's global compliance group, including in-country quality and logistics experts who ensure all aspects of the project comply with the highest quality standards according to robust standard operating procedures (SOPs).

Data objective monitoring and reporting

Real-time track and trace (RTTT) connects all components of the supply chain to facilitate tracking of all shipments on a digital platform. The Global GatewaySM portal allows customers to track inventory and progress against milestones and has an option to add sensors that transmit real-time shipment data to track location and temperatures. The TTM team also monitors the system to proactively intervene and resolve any shipment issues if necessary.

How TTM enhances clinical trial logistics



Integrated services

TTM's integrated service offering ensures consistency, reduces risks, and improves efficiency across all logistics processes. Specifically, choosing a logistics partner who understands the role of the IOR and who can act in this regard where possible is invaluable. At a minimum, the shipper, the courier, the importer, and the IOR need to be well-connected. The fewer providers involved in the supply chain, the easier it will be to track supplies through the process. The more integrated the service, the more efficient, cost-effective, and successful the project will be.



EMEA facilities and capabilities

TTM has a network of strategically located facilities in the EMEA. These facilities increase the efficiency of shipment to all regions and help ensure on-time and within-temperature delivery. Each of these facilities supports global clinical trials programs by offering RTTT, IOR, and customs services with in-country experts guiding each step.



Process efficiency

The process efficiencies gained by using TTM include reduced time from shipment to delivery and optimized routing. Increased efficiency is accomplished in part through Thermo Fisher's long history of tracking performance of couriers worldwide, understanding their strengths and weakness, and choosing the optimal providers for the needs of a given project. As part of the TTM service offering, Thermo Fisher coordinates the import and export processes while working closely with all stakeholders, including the designated IOR, the courier, and local customs officials. Thermo Fisher can liaise directly with each of these stakeholders about shipments, to preempt any potential hurdles and to take proactive measures, if needed, to ensure supplies get to sites and patients on time.



Risk reduction

TTM mitigates risks through continuous monitoring using RTTT. Clients have visibility and access to RTTT via the Global Gateway portal. The platform, along with a network of global experts (including project managers, couriers, the IOR, and QPs who actively communicate with each other), facilitates proactive problem-solving and ensures adherence to stringent regulatory standards.



Expertise and quality assurance

Every supplier associated with Thermo Fisher's TTM offering is vetted for their expertise and compliance with strict quality standards. The TTM Global Management Systems ensure logistics excellence, particularly in the EMEA due to a strategically located network of sites in the area. Leveraging that network of cGMP sites, including validated and redundant facilities with back-up generators to protect all products, and teams of logistics and other in-country experts, ensures that the TTM team is positioned to handle the entire supply chain from start to finish.



Case study 1: Optimizing global distribution

A leading pharmaceutical company with an extensive clinical trial pipeline struggled with frequent supply shortages and needed a comprehensive distribution strategy.

The customer needed support to manage global distribution and to overcome regulatory hurdles. They expected a solution that would reduce cycle time from order to delivery, reduce end-to-end logistics costs, and de-risk the supply chain. They also wanted to maximize visibility, control, and quality while reducing the burden on the sponsor's internal study management group.

The customer partnered with Thermo Fisher's TTM services who analyzed the company's study portfolio, transportation spend, required service levels, and delivery performance. TTM services helped the customer identify and contract with a strategic selection of couriers in optimal locations for their distribution facilities, ensuring the global reach required by the project. They also ensured oversight for third-party depot shipments and provided customs and regulatory guidance. TTM services also provided data-driven and objective monitoring that enabled proactive risk mitigation.

Because of their collaboration with Thermo Fisher, the customer increased their on-time in-full shipments by 4%, reducing overall costs by nearly 30% within the first 6 months of implementation. Partnering with Thermo Fisher's TTM services ultimately facilitated an estimated \$10.2M in annual savings for the customer.



Case study 2: Streamlining cold chain logistics

A medium-sized biotech company with a long-standing partnership with Thermo Fisher needed support with a new study involving temperature-sensitive materials shipped to multiple countries in the EMEA region.

The study materials required strict temperature control at ultracold temperatures. Any temperature excursions would alter the nature of the materials and make them unusable in the trial, posing a substantial threat to the project budget. In addition, the materials needed to be distributed to multiple countries in and outside the EU, and the customer was worried about how customs delays might affect at-temperature delivery.

TTM provided this customer with a solution including comprehensive cold chain management with zero time out of environment pack and ship and couriers with demonstrated expertise in ultracold transport. Thermo Fisher provided QPs where needed and served as the IOR in multiple countries to ensure that all applicable customs and regulatory requirements were planned for and met. Finally, the customer used the Global Gateway customer portal to track the location and temperature of their shipments, thus alleviating stress and concern.

As a result of their partnership with Thermo Fisher, the customer was able to make all of their study deliveries with zero temperature excursions and an improvement in time to market.



Case study 3:

Regulatory compliance in remote locations

A small pharmaceutical company planned a clinical trial program involving several sites in remote regions within the EMEA.

In planning their program, the company realized that navigating the complex import and export regulations as well as the languages spoken in these regions was beyond their in-house expertise and capability.

Because of its vast network of global partners and IOR capabilities in over 25 countries, Thermo Fisher was able to create a customized solution that included expert regulatory guidance for each involved region. TTM leveraged local partnerships with in-country language-proficient experts to ensure that shipments of clinical trials materials could take place efficiently and without delay.

The solution bolstered the capacity of the customer to conduct the research and manage the supply chain effectively. The materials received successful regulatory clearance without any delays to the trial timeline.



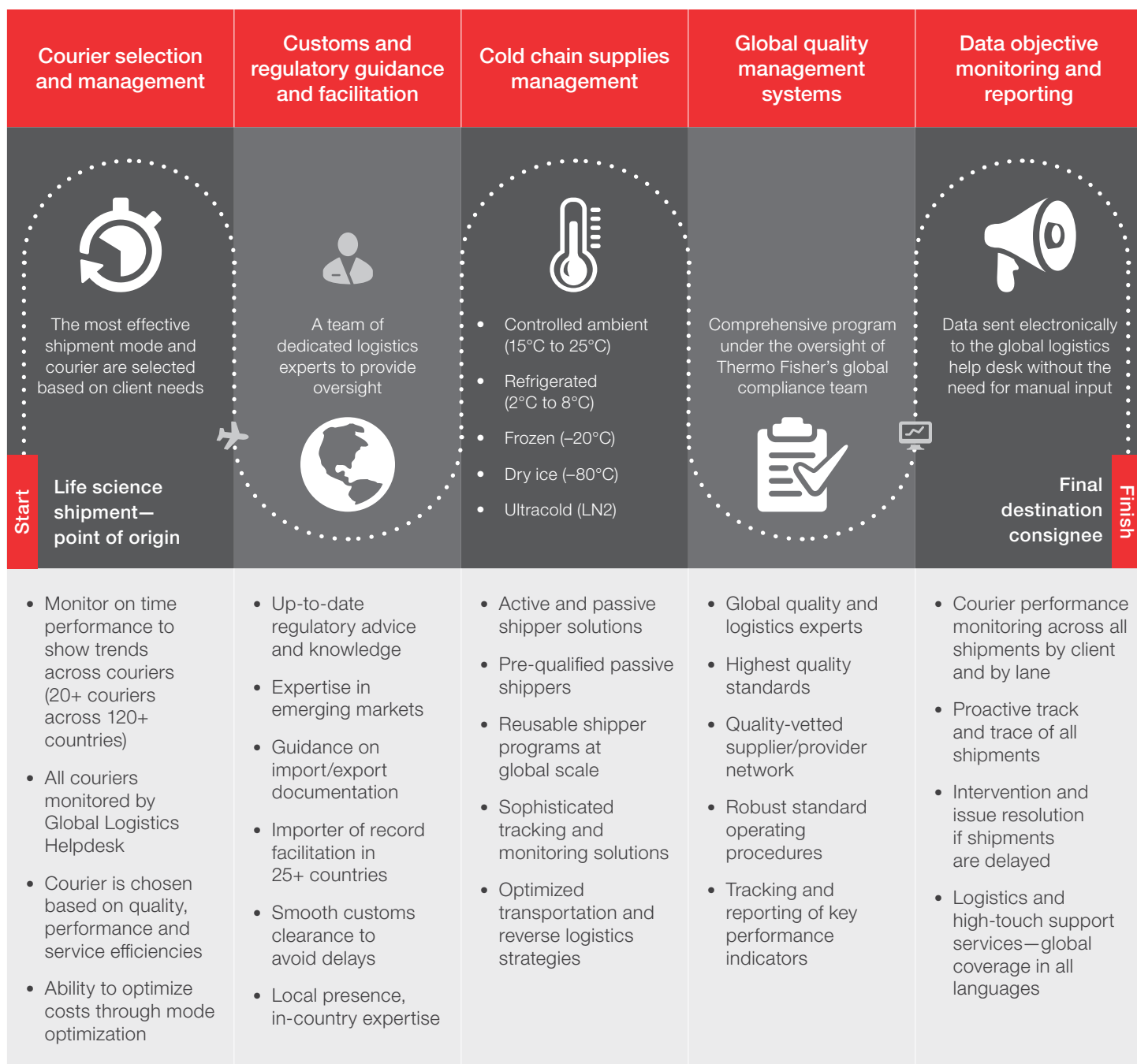


Figure 1. Thermo Fisher's Total Transportation Management: Delivering on time, in full, and at temperature.



● Clinical supply packaging and distribution: ambient to -80°C

● Advanced therapies with -80°C , LN2 storage, and shipping service

● Specialty distribution (finished goods; CAM)



30
purpose-built
cGMP facilities



>250
packaging
rooms



Qualified
Person (QP)
release



Local subject
matter
expertise



Strategically
located in
emerging
regions



Integrated
global IT
systems
and qualified
networks

Figure 2. Thermo Fisher's Total Transportation Management is a global service with facilities worldwide, including carrier networks and strategic EMEA locations. It also features a UK-based customs warehouse to facilitate the management of supplies to North America, South America, and Asia Pacific.

TTM's performance metrics

**30+
years**

of expertise in
moving, storing,
and managing
logistics for
clinical trials



Importer of record
capability in

**25+
countries**

400,000+

clinical supply shipments annually



Shipments to

**150+
countries**



98%

on-time delivery

Conclusions

As clinical trials and the drugs they are testing become more complex and as the race to market makes adherence to timelines even more critical, efficient and error-free supply chain management becomes even more important. Partnering with an organization that offers integrated logistics support and maintains a global footprint through strategically placed facilities and in-country experts can ensure project success.

Thermo Fisher's TTM services makes use of its vast network of vetted suppliers, cGMP facilities, and the most up-to-date technology to ensure that drugs reach their destinations on time and at-temperature. IOR and QP services provide sponsors with the assurance that all customs and regulatory requirements are considered and managed. Integrated global logistics services can result in substantial cost savings, improved reliability, and preservation of timelines, ultimately supporting faster development of medicines for patients who need them.

If you are interested in learning more about how Thermo Fisher's Total Transportation Management offering can increase efficiency and mitigate risk for your clinical trials program, please contact us for a consultation.

References

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3. Sykes, C. "Time- and Temperature-Controlled Transport: Supply Chain Challenges and Solutions." P & T: A Peer-Reviewed Journal for Formulary Management 43, no. 3 (2018): 154-170.

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