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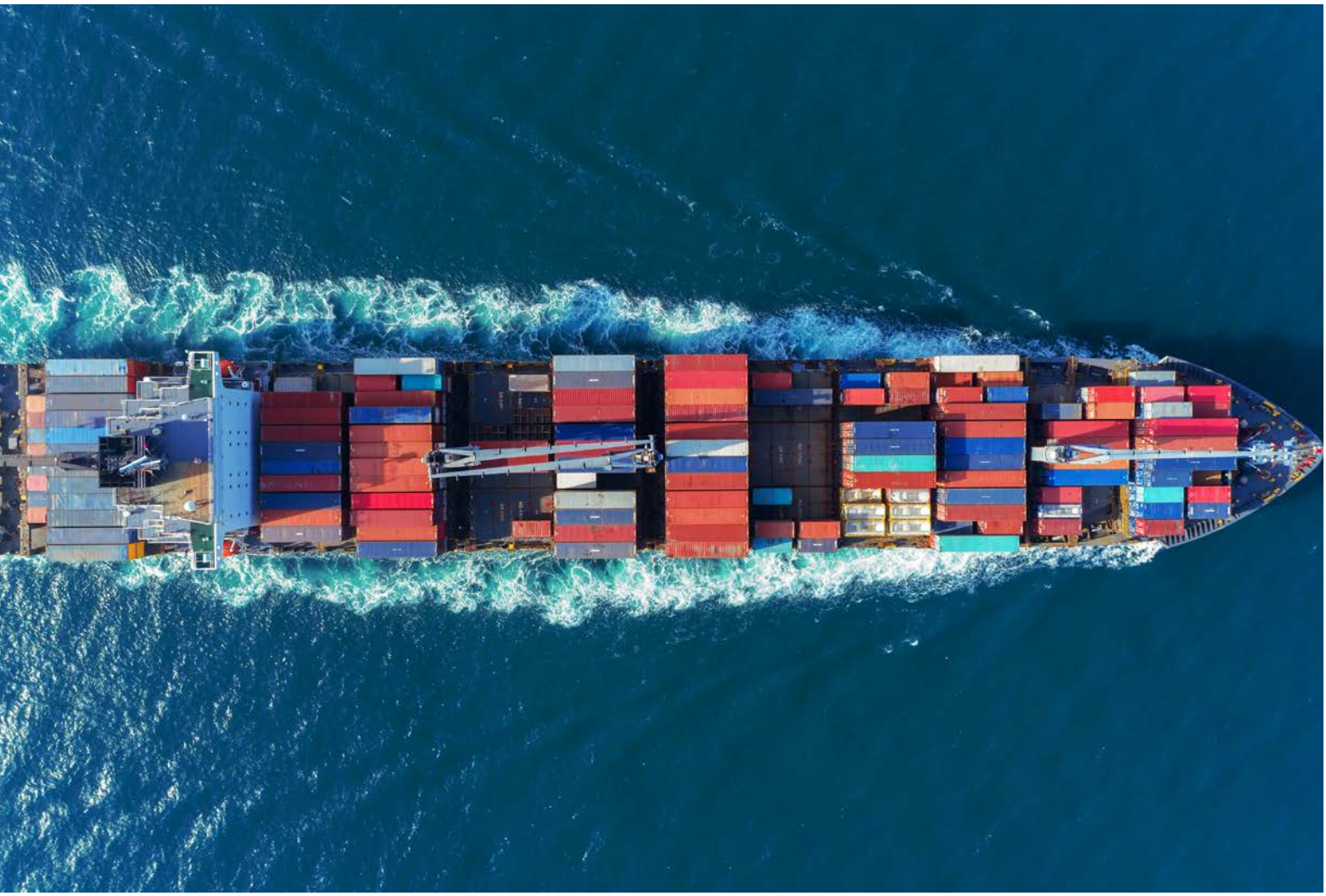

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WHITEPAPER

What clinical teams should know about changing trial logistics and how they will affect development

• API • BIOLOGICS • VIRAL VECTOR SERVICES • EARLY & LATE PHASE DEVELOPMENT • CLINICAL TRIAL SOLUTIONS • LOGISTICS SERVICES • COMMERCIAL MANUFACTURING

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Abstract

When it comes to clinical supplies, the journey is every bit as important as the destination. And these days, the journey of clinical supplies to investigator sites is becoming costlier and more complex, much like the global trials for which the materials are bound. The price of failure is high. A supply shortfall, or the inability to deliver needed supplies to clinical sites, can delay the start of a trial or cause an ongoing one to grind to a halt. Supply shortages can imperil an entire development program and prevent study patients from receiving the drugs a sponsor has committed to provide.

It's no wonder that supply chain logistics are estimated to account for as muchas 25% of total annual pharmaceutical R&D costs.[1] These cost pressures are projected to grow as a result of an evolution that is altering the clinical trial landscape and generating complex supply chain challenges. Some examples of that evolution in progress include:

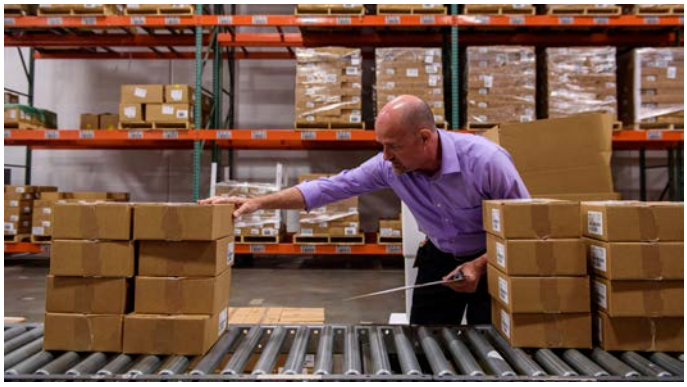
- The explosion of cold-chain products in development and move toward shipping even ambient products under temperature controls
- The continuing globalization of trials and impact of supplying trials in remote emerging market locations
- Evolving importation regulations and the potential fallout for imprecise documentation
- The soaring demand for comparator alongside concerns about safeguarding the integrity of the supply chain
- The growing interest in and potential of direct-to-patient studies (DTP)
- Emergence of what one supply chain manager has dubbed an "Amazon-like culture"
- The need for flexibility and contingency planning in a crisis-du-jour world

Much in the way that a GPS constantly adjusts to accommodate shifting traffic patterns and other obstacles, clinical supply chain logistics are adapting to accommodate these developments. In addition to discussing how supply logistics are changing, this paper contains examples of how Thermo Fisher Scientific is incorporating flexible solutions to ensure secure, efficient and cost-effective passage of clinical supplies.

Challenges and logistical costs escalate

"The more things change, the more they stay the same" could easily apply to the biopharmaceutical industry today. Despite the ever-evolving nature of the industry, drug development remains a lengthy, complex and costly process.

A growing list of challenges is constantly exerting new pressures on the industry: An aging population, the growing cost of healthcare, pressure from every quarter about the cost and safety of drugs, barriers to entry in emerging markets, the wider adoption of generic drugs and keen competition among companies, not to mention increasingly difficult therapeutic targets.[1]



Now, add to this list the burgeoning cost of logistics for clinical trials. Logistics spending has been on the rise and is projected to increase steadily. Spending on global biopharmaceutical logistics was $72.5 billion in 2014, increased to $78.8 billion in 2016 and is expected to reach $85.8 billion in 2018.

By 2020, such spending is projected to climb to $93.8 billion, driven in large part by cold-chain logistics.[2] Even with escalating logistical costs, the role of supply chain in the pharmaceutical industry remains underappreciated.

Only 39% of pharmaceutical respondents viewed the supply chain as an equally important part of business success as R&D, marketing and sales, according to a 2014 survey.[1] This leaves the industry warily eyeing escalating logistics costs and considering how to reduce them safely.

As a U.S. based supply chain manager put it, "Everyone wants to know what that secret sauce is in terms of getting drugs from Point A to Point B with the least amount of risk at the lowest cost."

Eye on supply chain: Logistics 2.0

Call them change-makers, transformers, disrupters. Whatever the name, the six developments discussed here were named by supply chain managers as driving the ongoing evolution in the clinical trial arena. Each of these developments is generating or will generate complex supply chain challenges that demand innovative, flexible and sophisticated solutions.

Falling temperatures

The explosive growth of biologics is making cold the new normal and cold-chain management one of the biopharmaceutical industry's major concerns.

By 2020, greater than half of bestselling drugs will be cold-chain products, most of which are injectable.[4]

Biologics have been nothing short of a resounding success story for the biopharmaceutical industry, heralded for making giant leaps forward possible in the long-term treatment of cancers, diabetes, rheumatoid arthritis, kidney failure and multiple sclerosis, as well as orphan and other diseases.

So it should be no surprise that the primary driver of supply chain costs is the explosion of therapies that require cold storage. In fact, there appears to be no end in sight.[2, 3]

By 2020, greater than half of bestselling drugs will be cold-chain products, most of which are injectable.[4] The growth of the global biosimilars market—which could reach $35 billion by 2020—is a key contributing factor.[3] Maintaining a secure cold-chain through storage, handling and transportation of temperature-sensitive drugs—some worth $1,500 per vial—ensures product quality and integrity and compliance with various laws, regulations, guidelines and codes.

Cold-chain handling is drawing increased regulatory interest, with both governments and industry updating cold-chain rules in the past decade and expanding the scope of temperature monitoring and control.[5] Shipping products, whether they must be maintained in the cold-chain or under controlled ambient conditions, is expensive.

To pack and transport materials in the cold chain, and to demonstrate by process qualification or by measurement that shipments remain cold, merely adds an additional level of complexity. In short, preventing temperature excursions comes at a cost—and costs are climbing.

In 2018 alone, logistics for cold-chain products are expected to cost drug makers $14.4 billion, a price tag projected to reach $16.7 billion in 2020.[2] This includes specialized tertiary packaging and instrumentation such as insulated boxes, blankets, phase-change materials, active temperature-control shipping containers and various temperature sensors and recorders. It also includes air, parcel and truck service.[4] Even as costs for cold-chain logistics skyrocket, an increasing number of products are likely to be transported under colder conditions. Regulatory authorities have indicated their preference for shipping all drugs under controlled temperature conditions.

A reason for this is differences in interpretation about what constitutes ambient conditions, according to one supply chain manager. A number of Asian countries, including China, considers 0°C to 30°C to be ambient. Meanwhile, ambient is defined as 15°C to 25°C under Good Manufacturing Practice (GMP) standards.

Sponsors are beginning to ship even ambient drugs, such as capsules and blister packs, under controlled temperatures accompanied by temperature monitors. There is also a move toward shipping temperature-controlled products as frozen shipments, making cold—and colder—the new normal.

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Fostering innovation

It's not a surprise that these developments are increasing the demand for cold-chain services and new packaging and temperature-monitoring technology. In 2018, 51% of our shipments were temperature controlled compared to a quarter of shipments five years ago.

The company is addressing these needs with continued investment in cold-chain storage, distribution capability and expertise across its global network, enabling it to handle growing quantities of cold-chain biologics across the globe:

- In Asia Pacific, Thermo Fisher more than doubled clinical supply cold-chain capacity for the region with the opening of a new 70,000-square-foot cGMP facility in Singapore and the expansion of the Tokyo, Japan facility.
- In 2019 the Suzhou, China facility has tripled in size with major expansions to refrigerated and frozen storage, as well as cold chain packaging suites.

- In Europe, the company doubled cold-chain capacity in Basel, Switzerland, and also became the first supply chain partner in the industry to make fully automated assembly and labeling of prefilled syringes from 2°C to 25°C. Introduced in 2017, this service is exclusively available at the Basel facility, where a dedicated cold facility maintains cold-room conditions from truck to dock, through assembly, storage and distribution.
- In Africa, Thermo Fisher extended the cold-chain capabilities of its clinical supply distribution facility in Pretoria, South Africa.

The company continues to explore and adopt new packaging and technology, including the use of robust, reusable shippers that reduce the burden on investigator sites and the environment.

In 2016, for instance, the organization partnered with a sponsor on a pilot program using a high-performance, phase change material (PCM) reusable shipper. The results were encouraging. In addition to resulting in a lower temperature excursion rate and greater contingency for delays than traditional, single-use shippers, the reusable shippers were lighter and cheaper to ship.

While more expensive, the reusable shippers compensated for a higher price tag by significantly reducing waste and environmental impact. The sponsor estimated that the use of reusable shippers would divert 300,000 pounds of waste from landfill in year one, with a targeted reduction of 1.2 million pounds diverted from landfill in year two. Investigator sites similarly gave their thumbs-up, citing the reduced burden and expense of shipper storage and disposal.

300,000 pounds of waste diverted from landfill in year 1

Targeted reduction of **1.2M** pounds of waste diverted from landfill in year 2

Increasingly global studies

Continued globalization is increasing logistical challenges as more clinical trials migrate to emerging markets. In pursuit of faster, less expensive recruitment for clinical trials, sponsors continue to target emerging markets. It is worth noting that most studies continue to take place in North America and Western Europe.

However, most of the growth in clinical research is taking place in Asia, South and Central America, the Middle East, Africa and Eastern Europe.[6] While an enlarged clinical trial universe undoubtedly benefits patient recruitment and diversity, it also multiplies the logistical obstacles for supplying studies.

Continued globalization is increasing logistical challenges as more clinical trials migrate to emerging markets.

In addition to inexperience in conducting trials and differing quality standards, there are widespread differences from country to country in customs knowledge, experience and laws. Many developing countries are also evolving regulatory requirements about the conduct of clinical trials and protection of research subjects. Some are implementing stringent new regulations for importation and clinical research.

Failure to adhere to these rules, particularly with respect to documentation, could derail timelines and budgets. In countries such as China, Russia and Ukraine, for example, failure to provide an acceptable rationale for product valuation can result in immediate and future headaches.

In addition to higher costs due to revaluation and a fine, the sponsor can look forward to having all of its future shipments "examined with a fine-tooth comb," as a United Kingdom-based supply chain manager explained.

CASE STUDY I

How an innovative transportation solution yielded efficiencies and cost savings

A leading multinational pharmaceutical company with an extensive clinical trial pipeline approached the Thermo Fisher Scientific team to develop a comprehensive, fully managed transportation strategy.

The sponsor chose us because of our Fisher Clinical Services℠ Total Transportation Management service, a solution that includes complete oversight of the supply chain processes required to move investigational medicinal product (IMP) shipments internationally and within countries of choice.

A cross-functional Thermo Fisher team, including specialists from Information Technology, Quality, Project Management, Engineering, Operations and Finance convened.

Their objective: Defining supply chain strategies to achieve a maximum percentage of ontime shipments and to realize cost efficiencies.

The team analyzed trial protocols, consulted a logistics database, evaluated data on couriers and applied data-driven objectivity to route and courier choice.

As a result of these efforts, the sponsor's original transportation strategy was changed to reflect a new approach to courier selection. This data-driven approach optimized cost and performance efficiencies for the sponsor, achieving significant cost savings.

Previously, the sponsor was sending 32% of its shipments via premium courier. Thanks to the data driven objectivity of our analysis, the proportion of shipments being transported by premium couriers plummeted to 7%, resulting in annual cost savings of $10.2 million. The Global Logistics Help Desk continuously tracked and traced all shipments. On-time shipments increased to 97% from 93%.

There is also the need to manage logistics complicated by countries' challenging climates and limited infrastructure. As previously discussed, studies of temperature-sensitive biologics present additional logistical challenges across the supply chain.

Missed dosing violates the commitment to serve clinical trial patients and can put their safety and well-being at risk.

Temperature excursions can exact significant drug and financial loss and missed patient dosing. Missed dosing violates the commitment to serve clinical trial patients and can put their safety and well-being at risk.

Finally, there are regional differences in language—both spoken and unspoken—working patterns, culture, and religion that add another layer of logistical complexity.

Fostering Innovation

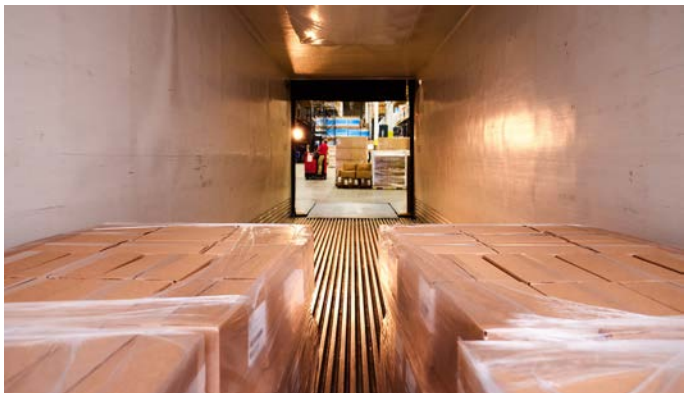
Thermo Fisher has one of the industry's largest network of purpose-built cGMP facilities strategically located around the world to support the conduct of clinical trials. These Good Manufacturing Practices (GMP) & Good Distribution Practices (GDP)–compliant facilities located across five continents provide the global presence, information systems and quality standards to ensure the flexibility, access and assurance needed for clinical trials.

This network of clinical trial supply and distribution facilities continues to grow. In addition to the expansions noted earlier, in the last five years Thermo Fisher doubled its presence in China to include a new facility in Suzhou, near Shanghai (2014) and opened a new facility in Seoul, South Korea (2016).

In 2019 the company opened a new facility in Buenos Aires, Argentina as well as a second facility in India within a Domestic Tariff Area, and the Suzhou China facility has now tripled in size.

Each facility is staffed with a team of highly trained professionals who bring a depth of expertise in managing clinical trials, from protocol design to site receipt of clinical materials. Add to this global expertise an understanding of local requirements and regulations, proficiency in the local language and English, and established working relationships with key parties across the supply chain.

Altogether, this allows the Thermo Fisher team to support the regulatory-compliant movement, management and delivery of supplies to more than 150 countries across all therapeutic indications.



Short supply

Soaring demand for reference drugs is generating innovative sourcing strategies that must also safeguard the integrity of the supply chain.

The escalating volume and complexity of global trials have driven the demand for reference or so-called comparator drugs to record levels. This is creating pressure to source sufficient quantities of comparator within tightening timelines and budget constraints.

In early 2017, for example, more than 236,000 studies were taking place in 195 countries, a number that has been climbing steadily, according to clinicaltrials.gov, the U.S. registry of clinical trials.[6]

As a result, the challenges of global sourcing for clinical trials have never been greater, particularly in emerging markets. Aside from the sheer number of countries involved in the typical clinical trial, a series of regulatory, supply and logistical obstacles magnify the challenge of sourcing comparators in emerging markets.

Many emerging markets are creating or evolving their regulatory infrastructures. In addition, some suppliers in emerging markets do not adhere to European or North American quality standards and requirements. Maintaining the integrity of the supply chain is another issue of concern. Drug counterfeiting is escalating worldwide, affecting both developed and developing countries.

China and India, two top-ranked countries for clinical trials, have also been identified as the sources of an increasing number of counterfeit drugs. The World Health Organization (WHO) estimates that up to 30 percent of the drugs sold in parts of Asia, Africa and Latin America are counterfeit.[7]

Fostering innovation

Thermo Fisher has a Fisher Clinical Services℠ Comparator Center of Excellence with a dedicated team of individuals focused exclusively on global comparator sourcing. This team takes the strategic approach of managing supply chain from day one through the conclusion of the trial by maximizing options and minimizing risk. They begin by assessing the specific risks and challenges in individual markets, and then identify ways to mitigate issues.

Direct sourcing of comparator from the manufacturer is almost always the best option because it establishes the shortest, most transparent supply chain, minimizing cost and the risk of counterfeit product. When sourcing from a manufacturer isn't feasible or desirable, however, the team turns to wholesalers and distributors that have been vetted in a rigorous qualification process.

The qualification process includes risk assessments of both the supplier and the country of sourcing. Supplier criteria include reputation and referrals, licenses, capacity, pricing and benefits, economic status and financial stability. The country of sourcing is key because some markets are safer than others.

Country criteria include whether the Regulatory Authority requires adherence to GMP, GDP and Certificate of Pharmaceutical Product (CPP) standards, legal provisions on marketing authorization, regulatory inspection of manufacturers and distributors, import control, and licensing and sanctions for violations of codes of conduct.

Another element is the frequency with which counterfeit drugs have been documented in the country. Ultimately, there is no one-size-fits-all sourcing solution. Every sourcing project requires a trial-specific strategy to deliver the best outcome.

An Amazon-like culture

The emergence of what has been dubbed an "Amazon-like culture" in the biopharma industry is driving the demand for 24/7 tracking of clinical supply shipments and the technology making it possible.

Now, sponsors want the same opportunity to track shipments in real-time and to obtain real-time data that they can analyze.

Purchasing goods from Amazon, the world's largest internet-based retailer, comes with knowing exactly where that order is at all times—from the time it departs the warehouse to when it can be expected to reach a customer's hands.

Now, sponsors want the same opportunity to track shipments in real-time and to obtain real-time data that they can analyze. Of course, clinical supplies are more precious than a book or DVD shipping from Amazon, which raises the stakes considerably. This has led to a growing focus on new technology, including temperature monitors with downloadable data logs, and the ability to access real-time updates on the location and temperature condition of supply shipments.

Fostering innovation

Thermo Fisher is investing heavily in their Fisher Clinical Services℠ offering, delivering information systems that can track shipments from warehouse to investigator, putting the company at the forefront of efforts to provide the comprehensive information sponsors require.

Cold-chain temperatures are monitored across the supply chain, giving sponsors the reassurance that product integrity is maintained at all times. Because the company handles a high volume of shipments via various carriers, we pride ourselves on basing supply chain decisions on objective data. Our Voice of the Customer research indicates that sponsors want 24/7 access through a portal to all their shipments in transit across the globe.

It is worth noting, however, that the desire to know the location and estimated arrival time of clinical supply shipments is not limited to sponsors. Investigator sites also want to know when to expect shipments, particularly those containing temperature-controlled products.

Patient centricity

Direct-to-Patient (DTP) trials are gaining the interest of sponsors and stand to become a bigger part of the clinical trial landscape. There could be no better example of patient-centricity than DTP studies. Some say that only a small percentage of clinical trials today are following the DTP model, but DTP studies have the potential to become a trial of choice for certain therapeutic areas or studies. DTP trials are a natural outgrowth of the growing trend toward self-administration of drugs, particularly for chronic diseases.

Whereas traditional clinical trials are conducted at investigator sites, whose staff provide trial medication to subjects during scheduled appointments, DTP trials eliminate the investigator site altogether. Instead, trial medication is delivered directly to the patient's home.

Due to the nature of the medication, however, in many instances a healthcare professional assists with drug administration in the home. In traditional clinical trials, the investigator site is responsible for collating data outcomes during the trial.

CASE STUDY

How a logistics team overcame the challenge of a crucial missing document

A crucial missing document can generate a crisis that threatens a clinical trial, as one resourceful Thermo Fisher Scientific's logistics team can attest.

A global pharmaceutical client purchased comparator for use by a clinical site in Russia. Unfortunately, the Certificate of Analysis (CofA) for the product was missing, creating a problem of monumental proportions: An umbrella license from the Ministry of Health is necessary in order to ship patient kits into Russia, and a CofA is required to grant the umbrella license.

The team contacted the supplier and the manufacturer, but neither could provide the CofA. Since Russia played a major role in the recruitment strategy for the trial, this put the study in jeopardy.

The Thermo Fisher Scientific team and client joined forces by teleconference to consider other options. After examining the documentation used to obtain approval for the clinical trial, they assembled a packet containing those supporting documents in place of the CofA. The packet of documents, together with a cover letter explaining the absence of the CofA, were then submitted to the Ministry of Health by the Thermo Fisher Scientific team.

The strategy succeeded. The Ministry of Health agreed to accept the supporting documents in lieu of the CofA and granted the umbrella license.

The Russian site received the supplies on time, the trial took place with no additional complications, and patients were not left waiting.

Sponsors usually appoint centralized data centers to collate study data for DTP trials. Not every study is appropriate for the DTP model.

The ideal profile includes a non-interventional study that does not require diagnostic testing prior to taking the study drug, a remote-study approach, a long-term outcomes study, non-ambulatory situations, rare diseases, and therapeutic areas that demand data collection from various stakeholders.

DTP studies are convenient and time-saving for patients, particularly those who are non-ambulatory, lack transportation or live in remote locations. There are shortcomings as well, however, chief among them reluctance on the part of some patients to self-administer drugs.

There are a great many advantages for sponsors. DTP studies improve the patient experience, leading to higher engagement and retention rates with better outcomes. From a logistics point of view, DTP studies drive efficiencies across the supply chain by reducing the number of handoffs and investigator site costs.

However, significant obstacles remain. Sponsors must still contend with greater transportation costs, thanks to a high volume of small shipments and the reverse logistics of shippers and biological specimens. Cold-chain supplies must be shipped to remote and often difficult to find locations in temperature-controlled containers.

Studies still need to be managed centrally by a remote study coordinator center. Finally, there is little regulatory guidance on designing and executing DTP studies, with rules varying from country to country.[8]

Fostering innovation

The Thermo Fisher team discusses DTP studies with sponsors on a case-by-case basis. Discussions begin with a careful review of sponsor responsibilities for DTP studies. For example, sponsors first must ensure that dispensing DTP is legal in the countries named in the protocol. Details of DTP distribution must be included in the clinical trial application (CTA) submission.

For countries that present import challenges or delays in clearing shipments through Customs, we recommend that the sponsor consider using local depots. The next step in the discussion is addressing the following questions:

- Does a licensed healthcare provider need to be present to receive and administer the medication?
- How can the sponsor ensure temperature specifications are maintained once the medication is delivered to a patient's home?
- What is the process for collating data?
- What simulates a prescription?

In light of the absence of regulatory guidance with respect to DTP studies and the inconsistencies from country to country, we recommend that sponsors proceed with caution.

A crisis-du-jour world

Flexibility and contingency planning have become the price of admission in clinical development. "Everyone is talking risk management," said a U.S.-based supply chain manager of his day-to-day interactions with sponsors.

It's no wonder. From supply shortages and natural disasters to terrorist incidents and acts of war, the news is a constant reminder of the need to be flexible and factor "what if's" into logistical plans.

Although clinical supplies were historically considered part of the execution phase of trials, they have become a key component of the planning process. With increasingly complex global studies taking place in challenging therapeutic areas, never has the need for flexibility in the supply chain been greater.

In an industry where circumstances change on a dime—countries are added or dropped mid-trial, an urgent need arises for new translations or additional regulatory reviews, or missing documentation puts supply shipments and trials at risk—flexibility means accommodating changes rapidly.

It is essential to be predictive, responsive and agile, according to a study by the Tufts Center for the Study of Drug Development, which described an ideal supply chain strategy as one that can provide study materials to any site within 24 hours.

As an individual at an investigator site put it: "I can work with a difficult or complex protocol even when I haven't been well trained. If a study is slow to enroll, I can figure out ways to increase our enrollment, but the one thing I can't work without is the drug itself. If there is no IMP, the study cannot go forward."

Fostering innovation

Flexibility and contingency planning are about ensuring that the right investigator sites and patients receive the right clinical supplies at the right time. Accomplishing this demands sound supply forecasting and the ability to maximize research efficiency through supply optimization.

Supply forecasting

In a survey of clinical trial professionals by the Tufts Center for Drug Development, better supply forecasting was listed as a top concern.

Although seemingly simple, supply forecasting is highly complex. Armed with a calculator and a protocol, it's logical to assume that determining the required quantities of IMP and comparator would be a matter of multiplication. It isn't. Relying exclusively on a mathematical formula for forecasting supply needs fails to factor in all that can go wrong to disrupt a supply chain.

Effective supply planning requires striking a balance between what's known and unknown, risk and budget, the needs of the trial and those of patients.

Planning effectively requires taking a multitude of variables from a variety of sources into consideration to create a supply plan that is flexible enough to withstand life's unexpected events and constant evaluation to make necessary adjustments.

Clinical Supply Optimization

Thermo Fisher supply chain managers factor in variables that include enrollment speed, milestone attainment, dating and extensions, material availability, blinding, distribution systems and numerous dosages, forms, sizes and shapes.

The team stresses that overage is not an indication of wasteful planning. Simulation can help to identify risks and potential areas for savings. Running out of materials can be more expensive than investing in some overage at the start of a trial. In other words, it's best to avoid being penny wise and pound foolish. Overage is necessary.

That's a key principle of our Fisher Clinical Services℠ Clinical Supply Optimization service offering. We use a strategy based upon ensuring that study drugs reach patients when and where they are needed while minimizing overall drug wastage and reducing risk.

Clinical Supply Optimization increases value while appropriately addressing risk—striking a balance between the quantity of drug that should be produced for a study and the risk of running out of drug during the course of the study, a situation known as supply stock-out. Stock-outs are costly because they jeopardize patient safety, the success of a study, and the sponsor's reputation and relationship with influential clinical investigators.

Proactive and comprehensive from strategic planning through execution, our Fisher Clinical Services℠ Clinical Supply Optimization service offering encompasses all elements of supply chain management, including:

- How much drug should be manufactured and when
- How much comparator is needed and the most appropriate sourcing strategy
- How to optimize supplies of study drug and comparator
- How to package, label and transport study drugs for maximum efficiency at minimal cost
- How to ensure that clinical trial supplies reach clinical sites when they are needed
- How to monitor drug supplies and patient enrollment to avoid stock-out

Looking Forward

How to manage changing trial logistics

- **Start early.** The time to begin discussing supply logistics is while the protocol is under development. Although that might appear premature, early planning translates into maximum options.
- **Identify vulnerabilities.** Ask questions and brainstorm potential logistical problems with the clinical team and a trusted supply chain partner. Identify the areas that may require special attention.
- **Opt for maximum flexibility**. Build the vulnerabilities that were identified – call them the "what if's" – into logistical plans. If you aren't convinced that that's necessary, ask yourself this question: How often has anything ever gone exactly as planned?
- **Weigh options.** Choose a supply chain partner with the knowledge, experience, breadth of services and global footprint necessary to address vulnerabilities with flexible solutions.
- **Forecast with care.** Bear in mind that running out of materials can be more expensive than investing in some overage at the start of a trial. While no one advocates wasting drugs, experience has established that some overage is necessary.

Remember the patients. Clinical trial logistics are aimed at ensuring that the right drug reaches the right patient at the right time. Conducting a trial comes with a commitment to serve trial patients—imagine your parent, grandparent, child or friend—by putting their safety and well-being first.

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About us

Thermo Fisher Scientific provides industry-leading pharma services solutions for drug development, clinical trial logistics and commercial manufacturing to customers through our Patheon brand. With more than 65 locations around the world, we provide integrated, end-to-end capabilities across all phases of development, including API, biologics, viral vectors, cGMP plasmids, formulation, clinical trials solutions, logistics services and commercial manufacturing and packaging. We give pharma and biotech companies of all sizes instant access to a global network of facilities and technical experts across the Americas, Europe, Asia and Australia. Our global leadership is built on a reputation for scientific and technical excellence. We offer integrated drug development and clinical services tailored to fit your drug development journey through our Quick to Care™ program. As a leading pharma services provider, we deliver unrivaled quality, reliability and compliance. Together with our customers, we’re rapidly turning pharmaceutical possibilities into realities.

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