Effective Optimisation and Cost Management in Clinical Trial Logistics

Historically, clinical trial distribution was focused on product protection and patient safety at any cost. More recently, just as their counterparts in commercial distribution are facing significant pressure to reduce the cost of cold chain distribution, increasingly over the past several years there has been a significant shift within the clinical trial sector which is adopting more cost-effective processes and operating more and more like commercial colleagues.

Within clinical trials, we've seen a tightening down and expectation of reducing costs in cold chain distribution. The sector as a whole seems to be looking much more closely at optimisation and cost management versus the past, when it was based on whatever measures were necessary to get the job done.

When focusing on cost reduction, it is important to look at the total picture. Most in the industry will agree that secondary packaging comprises approximately 20% of total logistics cost, while the actual transportation makes up the other 80%. So, one must look at not only the cost of the temperature-controlled packaging, but the overall cost of transportation, packaging and other services combined.

More recent technological advancements in temperature-controlled packaging introduced to the market has seen the utilisation of more innovative technology, such as improved insulation incorporating vacuum insulated panels (VIPs) reducing the thickness (dimension) of the insulation required and driving greater performance. In addition, traditional, more antiquated water-based systems are rapidly being replaced with systems using a variety of phase change materials (PCMs) that are capable of solidifying and melting (storing large amounts of energy) at specific temperature points to support the ideal temperature range required.

The latest advancements mean shipper systems using VIPs and PCMs are far more reliable, a critical requirement for clinical trial companies, while providing more stability within the packaging at the desired temperature and using less overall material.

As opposed to more traditional water- and foam-based thermal packaging, more innovative thermal packaging that leverages advanced insulation technologies such as VIPs and PCMs for cooling can provide not only better performance and protection, but can do it in a more volumetrically efficient manner. The result is that while the initial purchase price of the box may be more, the total cost of a shipment may come out to be more cost-effective if you consider all costs involved, especially transportation.

Thermal performance and protection are often more critical in the clinical space, thus driving them to seek out better performance packaging. Usually the superior performance resides in higher-end packaging such as the more innovative packaging with VIPs and PCMs. These advanced technology containers can often require a larger upfront investment.

As mentioned earlier, however, it is not just the cost of the packaging that should be considered but the overall cost of ownership and use, which includes all the inbound transportation, the outbound logistics, potential return logistics. So, the consideration of all the logistics factors is critical, but the consideration that can be a game-changer is centred around product protection and ultimately patient safety.

Given the potential cost advantages of more advanced technology, one is then able to take advantage of the likely enhanced performance. Optimisation and cost management should be looking closely at the value associated with eliminating product temperature excursions and the significant costs associated with product loss, quality investigation of an excursion (estimated by many to be in the $4K–$6K range per incident for a parcel shipment) and, most importantly, the potential delay of a trial due to reduced efficacy of a treatment.

There are significant costs associated with any temperature excursion, especially in the clinical world, and the associated repercussions. This includes the cost of potentially replacing product, in addition to the cost of the quality investigation that needs to happen to understand the root cause of the excursion. Also, there are the potential delays in time to market from a trial standpoint. These associated costs around temperature excursions, product protection, and patient safety can be significant.

Another critical consideration is to ensure the packaging being deployed is easy to use. If packaging is difficult to use or to pack out, that complexity can also lead to an excursion. There are some products on the market which are difficult and complex to pack out because things have to be done in a certain order for different temperature requirements and at different times of the year.

There are many other considerations that can be optimised as well, which have to do with the human element and expertise, such as conditioning and preparation of the coolants. Clinical sites may not have as much experience of working with the conditioning requirements of advanced PCMs, as an example. It might be decided that they want to outsource that capability to their packaging or service provider, as there are some costs associated with having some



conditioning equipment and knowing how to use it correctly within their own facility.

So, from an excursion and product protection standpoint, ease of use and pack out, as well as other operational support requirements, are an essential element to take into account so you potentially eliminate human error, which can often account for up to 50% of the excursions that occur.

As technological advancements within higher performing, pioneering packaging alongside more simplified pack-out processes continue to assist with optimisation and cost management considerations within the clinical sector, technology also plays a pivotal part when it comes to monitoring payload which are often time- and temperature-sensitive.

Increasingly, advanced information technology is available to clinical groups, which can be utilised to track the packaging deployed in real time or capture data once the shipment reaches its destination.

Real-time monitoring could be used to know quickly if a shipment has, or may have, a temperature excursion, or will be delayed from reaching the patient; therefore allowing a new shipment to be sent out quickly to the patient, with the original being reclaimed or disposed of, depending on its status.

IoT solutions, GPS tracking and temperature monitoring are increasingly providing vital assistance in global clinical trials transportation, enhancing the protection offered by advanced temperature controlled packaging solutions.

In the case of reusable technologies, in a bid to help in the recovery of these assets, companies are also increasingly utilising advanced asset management software systems to ensure time- and temperature-sensitive payloads are shipped to the right location, at the right time and critically, that they arrive in the right condition, and are returned as planned.

Reuse is probably more accepted and common in the clinical space. The reason is that one of the big values in reuse is it drives down the cost per use, but what it really does is give access to much better technology. Clinical trials organisations can afford much better technology because the packaging cost is driven down (on a per-use basis) based on the reusability.

We are seeing more and more situations where companies don't necessarily need to own the actual assets. They are increasingly attracted to a model where they can just pay for the use of a box and the packaging vendor maintains ownership, whether that's via a lease programme, rental, or pay per use.

That's become a very attractive model whereby there is no real value in owning the asset. So, the packing provider can own the asset and provide services surrounding that asset, while the clinical trial company pays a single monthly bill based on the overall use required.

It is critically important for a clinical company to partner with a packaging provider that has an established global network and infrastructure in place to support this reuse.

If clinical organisations are going to access the better packaging technology that they need, they are going to leverage the advanced technology to keep the cost under control and in order to be successful, they need a packaging partner who can not only assist in ensuring recovery of the packaging assets, but also provide support with the infrastructure to service any reusable containers deployed, i.e., to inspect, clean, repair if needed, and even provide conditioning services and support on a global basis as required.

While many in the clinical world will rely on the speciality couriers in the early Stage 1 and Stage 2 trials, they often will modify their transportation or logistics approach to keep closer control and transparency when their pharmaceutical under clinical trial progresses to the higher volume stages associated with Stage 3 trials and beyond.

As the clinical trial organisations anticipate with the added complexity in getting cold chain logistics done right, they look to bring activities 'in-house'. However, they will look to leverage partners that can provide not only the advanced packaging solutions, but many if not all of the associated services involved in a complete offering, such as warehousing, conditioning of coolants, refurbishment and repair in the case of reusable technology, and even transportation services if applicable. The goal is to drive quality and to simplify where possible.

Accessing optimised shipper solutions, which are high performing and advanced technically, not only helps mitigate the risk of excursions, but they are by design also going to be lighter and take up less space in general than heavier, traditional systems, while offering cost savings during transportation.

So it is a case of considering not just the cost of the packaging but looking at the overall cost of ownership, which includes all the inbound transportation, the outbound logistics and return logistics and all the logistics factors associated with that, and the one that can be a game-changer is centred around product protection and patient safety.

Whatever future developments transpire within the industry, alongside more complex transportation challenges, the temperature-controlled packaging industry will continue to respond with increasingly innovative shipper solutions, asset management, and monitoring systems to better protect the precious payloads designed to save, heal and enhance lives.

Temperature-controlled packaging providers continue to produce innovative products that are increasingly advanced, and deploying high-performance, protective packaging in clinical trial transportation is critical to the clinical trial market.

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