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Challenges Of Temperature Control
In Direct-to-Patient Shipments

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Enrolling patients in clinical trials has become an increasingly challenging task. From the globalization and diversification of trials to the COVID-19 pandemic and its resultant limitations on providers and patients, the constraints on traditional on-site clinical trials are more burdensome than ever.

In response to these challenges, decentralized clinical trials (DCTs) have become an increasingly popular alternative to traditional trials. These trials, which augment more regimented, in-person approaches with adaptive, data-driven alternatives, have seen increasing adoption in recent years, galvanized by the COVID-19 pandemic and an increasing emphasis on patient-centered and at-home care.

But just as with typical clinical trials, DCTs present a number of challenges for sponsors. One of the biggest hurdles inherent to the DCT paradigm lies in ensuring the safety and viability of samples collected from, and treatments shipped directly to, patients. Direct-to- and direct-from-patient shipments differ from larger scale cold chain shipments in a number of ways. Finding the right container and supplier to navigate the intricacies of direct-to-patient and direct-from-patient shipments is critical, particularly for DCTs, bespoke biologic treatments, and vulnerable patient populations.

The Growth of Home Collection Packaging

The focus on enabling cold chain shipping across a range of scales has accelerated rapidly in the wake of the pandemic. This has, in turn, led to new models for clinical trials – to fast-track trials for the COVID-19 vaccine, one large cold chain shipping company proposed a home collection model to provide samples for studies. The success of this model in expediting trials has resulted in a more widespread adoption of samples collected directly from patients; as a result, direct-from-patient shipping now represents one of the biggest segments of the company's business.

While direct-from-patient shipments typically involve sample collection, whether blood, urine, stool, tissue, or saliva, direct-to-patient packages often include temperature-sensitive therapeutics, which require stringent containment parameters to prevent temperature excursions. Although data logging technology that tracks temperature is not a common feature of many home collection packaging solutions, that paradigm is likely to shift in the near future, as more cell and gene therapies become the standard of care for many conditions. This is particularly important for autologous cell therapies; because these bespoke therapies are made by harvesting cells directly from the patient, their cost and manufacture necessitate careful handling and transport.

For larger shippers moving multiple doses of a drug, the normal process that attends those shipments, from container conditioning to temperature logging, often becomes rote. But direct-to-patient and direct-from-patient shipments, by their very nature, come into contact with patients and others who are unfamiliar with typical pharmaceutical handling practices. As a result, the container design for these types of shipments must account for that unfamiliarity. Some companies have worked to solve this issue through packaging that requires no conditioning prior to shipping, as well as other design elements to improve ease of use for patients. Though the majority of these systems are used for sample collection, their resilience in the face of potential user error, weather conditions, drops from height, and other variables is critical to enabling their widespread utility.

Designing Fail-Safe Shippers to Optimize Trials

The central consideration for a company or trial sponsor looking to incorporate home collection shipments into their transportation strategy is validation. Ideally, a shipper is tested and qualified to ensure that it can maintain the quality of a sample under a range of potential shipping conditions. This qualification is critical, particularly for rare disease trials, where every patient sample may represent an irreplaceable piece of data for researchers.

The parameters regarding temperature ranges are often even more stringent in a clinical trial setting, where a lack of the data that accompanies already commercialized drugs translates to an abundance of caution. A strict temperature range may become more flexible as more data comes in to help developers understand a therapeutic's limitations, but until then, the risk of a shipment falling outside that range is an unaffordable one. To accommodate this uncertainty, most trial sponsors will opt for solutions that offer the greatest possible thermal protection and reevaluate their shipping paradigm in later stages of development to identify where shipping may be simplified. Designing a shipper that can maintain a narrow temperature range without requiring outside support is core to enabling DCTs and at-home sample collection more generally. But it isn't the only consideration; as more DCTs are launched and more home health alternatives pioneered for vulnerable patients, the need for lighter, smaller, simpler home collection shippers has only increased.

The entire pharmaceutical landscape has experienced a marked increase in DCTs, both because of the physical and logistical constraints presented by the pandemic and the relaunching of the numerous trials suspended at its start. This has resulted in concomitant investment from shipping companies and suppliers, in order to increase both the infrastructure and capacity needed to support growing demand. Alongside these considerations should be a continual commitment to incremental improvements in design, efficiency, and sustainability for these systems in order to accommodate a greater range of customers and applications.

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The Future of Direct-to-Patient Shipments for Biotherapeutics

Direct-to-patient and direct-from-patient shipments have evolved considerably in the last few years, but there still exist a number of challenges to their more widespread adoption. One of the biggest challenges, particularly for direct-to-patient shipments, was again evidenced by the COVID-19 pandemic – the ultra-cold temperatures required for vaccine distribution made the technology widely employed by these shippers infeasible. Facilitating ultra-cold shipments is already a difficult proposition, even for larger or more advanced shippers. This is because the temperatures needed to maintain these drugs require the use of dry ice or liquid nitrogen, creating an insurmountable burden for packages handled by mainstream shipping companies, healthcare providers, and patients.

This issue is even more pronounced for certain cell and gene therapies, such as CAR-T therapies, which can require storage at temperatures in excess of -150 C°. These ultra-low temperature requirements make certain DCT models impossible for these kinds of therapies at present. Surmounting these challenges will require a substantial, long-ranging investment in the containers and technologies involved, as well as a focus on understanding the role patient experience has in informing these technologies.

Ultimately, the increasingly complex protocols that attend modern clinical trials, coupled with the needs and preferences of the patients involved and the logistical challenges introduced by the pandemic, have made direct-to- and direct-from-patient shipping crucial tools for providers and trial sponsors alike. Data to date shows that DCTs boast a somewhat higher enrollment rate than traditional clinical trials; retention and compliance among patients is also frequently improved by offering home health services in place of a trial site. As the demand for temperature-sensitive samples and therapeutics continues to rise, facilitating these solutions through a supplier with the expertise and experience needed to grow alongside development is integral to advancing the biopharmaceutical industry's impact and reach.

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