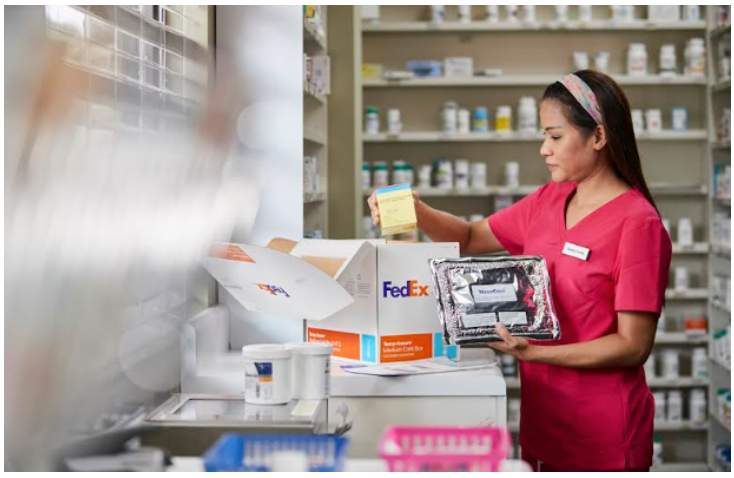
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The lasting benefits of decentralized clinical trials logistics

08 October 2021 | Features | By Kawal Preet, President, Asia Pacific, Middle East and Africa (AMEA), FedEx Express

The global pandemic has been a catalyst in transforming how clinical trials are run. A decentralized trial framework backed by enhanced logistics, improves patient sign-ups, and ensure trials continue uninterrupted â?? all benefits that can be reapplied in a post-COVID world.



Pre-pandemic, the Asia Pacific region was already becoming a preferred destination for clinical trial studies[1] Positive changes in clinical research regulations, reduced costs to run trials, and large urban-centered populations[2] were all helping the sector advance at a respectable 8% CAGR.[3]

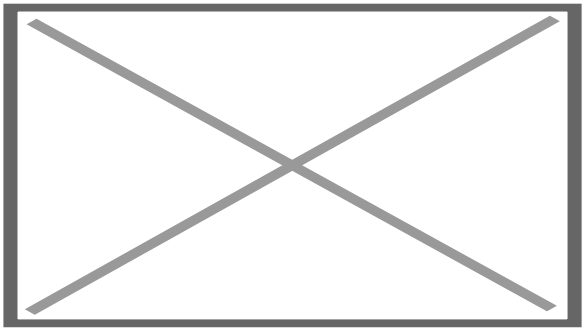
COVID-19 disrupted how trial sites, stock management and data collection are being managed. At the same time collaboration among governments and research authorities for vaccine development improved dramatically and demand for clinical trial supplies spiked.

To keep clinical trials on schedule, life sciences companies are shifting towards a decentralized[4] model. Using direct-to-patient logistics combined with remote technologies for data collection helps keep participants safe from the pandemic over the immediate term. But the approach also supports a high patient-retention rate that will be a boon to all clinical trials in the long-term.

Reliable logistics support critical to the decentralized model

Decentralized clinical trials and their associated direct-to-patient service benefits call for flexibility, reliability, and integrity in the supply chain. The logistics provider is expected to deliver, distribute, and retrieve clinical trial supplies and sensitive biological materials directly to and from the patients' locations.

Life sciences companies are cost-efficient in clinical supply logistics and conscious of optimizing production and packaging. As a result, most of them are looking to build partnerships with trusted logistics companies who can deliver temperature-sensitive shipments to a wide range of locations safely and seamlessly, while providing assurances to protect the integrity of biological samples and reduce wastage.



Logistics providers like FedEx have been using their extensive global network of cold chain capabilities to transport biological samples safely with near real-time supply chain visibility. Take COVID-19 test samples, for example. In March 2020, at the beginning of the COVID-19 outbreak, FedEx transported more than 20,000 COVID-19 test samples safely in less than 24 hours from 50 test sites to labs across ten states in the U.S. Till date, we have delivered COVID-19 vaccines to 50 countries around the world. The successful management of delivering mission-critical trail samples contributed to the development of COVID-19 vaccines, which were made available by late 2020.

Safeguarding the Integrity of Clinical Samples and Reducing Wastage Remains Key

Shipment integrity in clinical trial logistics is governed by temperature sensitivity. Studies have shown that up to 30% of clinical trials samples are wasted in warehouse when shipments are being loaded.[5] In order to prevent such wastage, logistics providers need to provide temperature control solutions at an early stage and ensure the consistency throughout the process. FedEx built its Healthcare Priority solution using a portfolio of refrigerated, frozen and perishable shipping options for moving clinical shipments in a safe, temperature-controlled environment, protecting supply chain integrity.

Part of the FedEx portfolio includes reusable thermal packaging like MedPak VI°C that offers up to 96 hours of temperature stability in case of unexpected events. End-to-end tracking technologies offer continuous visibility of sensitive clinical shipments. The latest state-of-the-art solution in shipment tracking is SenseAwareID, which is an in-package sensor designed to provide healthcare customers with updates on a package's location in near real-time allowing them to plan ahead of delivery.

All of these healthcare-specific solutions are backed by a global network of 670 cargo aircraft, 5,000+ facilities and over 180,000 transport vehicles. This has allowed FedEx to flex its network and keep shipments moving despite the recent

contractions in air cargo capacity that have affected other carriers.

Navigating Complex Regulatory Compliance is Critical

Most pharmaceutical companies have increasingly expanded operations across developing and developed countries. Because of this, complexities in supply chains have increased, and scrutiny from regulators has intensified. Since quality assurance and adhering to regulatory compliance are critical to the successful delivery of clinical trial shipments, getting all processes right at every link in the chain ensures a competitive advantage for logistics providers.

For any life sciences companies, when it comes to choosing a logistics service provider, support in navigating existing and emerging regulatory frameworks and the ability to navigate new challenges on behalf of customers are critical factors in their decision-making.

Built on decades of experience in clinical trials shipments, FedEx healthcare team has in-depth knowledge of multiple regulatory environments and expertise in handling logistical complexities across different territories. Its Healthcare Quality Management System are designed to meet the industry's unique requirements and provide a detailed audit trail throughout a shipment's journey.

Innovation: The Way Forward in Clinical Trials Supply Chains

The COVID pandemic has forever changed how we plan risk management. To build a future-proof healthcare supply chain, the logistics sector needs to go all-in to leverage advanced technologies to ensure effective delivery while increasing efficiencies and reducing costs. Automated robotic devices like Roxo™, the FedEx SameDay Bot are being introduced to respond to evolving same-day delivery needs, while data-driven supply chain analytics and forecasting are becoming possible with AI-powered solutions like FedEx Surround.

Looking ahead, as countries are still in various phases in the battle against the COVID-19, the decentralized clinical trials are here to stay. What it means is that providing best-in-class clinical trial deliveries goes beyond commercial interests. The world relies on key industry players, including logistics services providers, to help contain the virus. To facilitate the shift to the 'direct-to-patient model, logistics companies play a critical role in ensuring delivery safety, security, timeliness, and cost-efficiency.

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[1] https://www.clinicalleader.com/doc/the-asia-pacific-region-a-hot-spot-for-clinical-trials-0001

[2] https://novotechcro.com/sites/default/files/170217_FrostSullivan_Asia%20white%20paper_full.pdf

[3] https://www.researchandmarkets.com/reports/4479432/clinical-trial-supply-and-logistics-market#

[4] https://www.pwc.com/us/en/industries/health-industries/library/decentralized-clinical-trials-qa.html

[5] https://www.ns-healthcare.com/analysis/waste-not-want-not-100918-6745323/