Controlant

Optimizing Cold Chain Logistics and the Clinical Trial Supply Chain

— Real-time Insights

As sponsors run increasingly complex clinical trials while seeking rapid decisions on the viability of their treatments, technology plays a crucial role in the transport and storage of clinical trial materials. Cryogenic and other temperature-critical distribution and shipping of cell-based products come with many challenges and issues not faced by traditional pharmaceutical products and the commercial supply chain. Movement of investigational products, patient samples, and the therapies themselves all require exact, time-limited logistics enablement, which melds an understanding of the therapy, the patient, and how logistics, technology, and packaging choices intertwine. These priceless, innovative treatments require innovative comprehensive cold chain solutions.

As you know, the supply chain is rarely linear. Supplying a worldwide trial can produce rocky developments and uncertainties that can escalate down the entire clinical trial supply chain. With the focus on efficiency and patient safety, you cannot afford errors or omissions in managing this complex global supply network.

Holistic supply chain management reduces risks and surprises, enables responsiveness and flexibility, and facilitates cooperation and strong partnership between technology, logistics, and manufacturing. The success of these trials—and ultimately commercialization—critically depends on maintaining optimal performance conditions of these temperature-sensitive products throughout the trial. It is imperative to maintain an efficient and e ffective clinical trial supply chain while maintaining compliance with complex regulations.

Leveraging real-time technology can help stakeholders identify and solve problems, optimize the supply chain, reduce costs, and ensure that the trial begins on time and the new medication is available at the appropriate sites for new patients. Because change **will** occur during most clinical trials, transparency creates the ability to anticipate and respond to changes, while allowing for continuous supply chain improvement.

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Clinical trial supply chain challenges

Regulatory complexity

Global trade regulations are a particular challenge for the clinical supply chain. These can prevent movement of product between sites, delay delivery of supplies to sites—a particular issue when there are short expiration dates—and even potentially un-blind trial supplies. Repeat infringement of trade regulations can also result in substantial fines and penalties, and potentially more significant regulatory sanctions. These and other regulatory requirements keep regulatory compliance as a primary concern.

As per the Good Manufacturing Practice (GMP) Regulations, all investigational products need to specify storage conditions and expiry dates as specified by the results of stability testing. Clinical trial materials are also subject to Good Distribution Practices (GDP) and Good Clinical Practices (GCP). As regulators increase scrutiny to ensure patient safety, many issues arise involving the transport, storage, and distribution of medical products. Companies need to ensure that the product remains safe and accountable during transportation and storage while evaluating product handling requirements, transportation lanes to be used, container availability, and cost.

Transfer and storage of temperature-controlled clinical trial materials

The success of clinical trials is heavily dependent on providing study supplies to often large numbers of sites so that drugs can be administered at the correct times throughout the clinical study. Issues such as supply stock-outs can result in patients being disqualified, potentially jeopardizing the entire study. However, forecasting of trial stock requirements is difficult, particularly with the rise of adaptive trials. Patient recruitment occurs at different speeds and patients sometimes drop out of trials before study completion.

Achieving an agile supply chain is imperative to meet the ever-changing clinical trial demands. Ensuring drugs are stored, handled, and transported according to pre-determined conditions is an increasing challenge as this demand increases. Traditionally, refrigerated and ambient investigative product shipped would contain a temperature monitoring device, which, upon the end destination, would be manually checked and recorded. Problems and their root cause couldn't be identified until the end of a shipment, if at all. In addition, temperature loggers used for the supply chain often could not capture quality information of goods stored in a refrigerator or freezer, and immediately alert personnel if a temperature deviation occurred. Today, the ability to connect temperature and location data through real-time monitoring technology helps shed light on issues as they occur that can impact product quality. Real-time alerts help to facilitate proactive corrective response, while automatically documenting supply chain temperature data for compliance purposes.

Temperature excursions

Avoiding temperature excursions while clinical trial materials are in transit and inside refrigerators and freezers is imperative throughout the clinical trial process. A single technology solution that can travel with products from manufacture through the last mile storage helps streamline the process and provides validated, electronic support for audits as well as for the internal SOPs that must be followed. Where investigational products are stored outside of the predetermined temperature conditions, logistics partners, investigators, research nurses, and clinical research associates need to be promptly notified with data that supports a determination of the root cause as well as corrective action that needs to be taken.

Our partnership approach: Cold Chain as a Service

Controlant's real-time cold chain temperature monitoring solution automates supply chain data capture from manufacture through the last mile, including onsite in pharmacies and clinics. Our solution is threefold, and consists of a combination of IoT hardware, software, and services, offered on a pay-as-you-go, subscription basis. Supply chain data is captured in real-time through wireless and reusable IoT data loggers and automatically sent to a cloud-enabled software platform, where clinical trial supply chain information can be viewed on demand and shared with stakeholders.

Data analytics provide insights regarding risks and trends, lanes, packaging, route performance,

and other points of interest, to drive continuous improvement, leading to greater operational efficiency and cost savings.

Our managed and professional services make it easy and cost-effective to scale real-time temperature monitoring and visibility across the entire clinical trial supply chain.

Mapping and process

- Packaging and lane validation
- Mapping and installation
- Change control and SOPs

Monitor

- Real-time, continuous monitoring and chain-of-custody data
- Monitoring of moving products and onsite for refrigerators and freezers
- Data is automatically sent to a cloud-enabled software platform
- Live notifications and alerts (in-app, email, SMS)
- Integrates with other business systems
- Individual certificates and NIST/UKAS
- + / - 0.5C measuring accuracy
- Standard Temperature Range: -20^{0}C to +50^{0}C
- Low and Cryogenic Temperature Ranges: -80^{0}C, -200^{0}C

Manage

- 24/7 monitoring and response services
- IoT asset management and servicing (including annual calibration and repair)
- 24/7 global support, 365 days per year
- Training and program management

Measure

- Alert overviews
- Route, packaging, and lane performance
- Statistics and trends
- Product and cost savings

Conclusion

The goal of an optimal clinical trial supply chain is ensuring that the right technology, process, and people are in place so that a sufficient supply of investigational product arrives at the right time, at the right location, and in a cost-effective manner.

Temperature monitoring is a mission-critical piece of the puzzle. The underpinning technology should be flexible and equipped with options to manage changing needs, and easy to use by site personnel. The automation of data can accelerate decision-making through high visibility to data, eliminate duplicative reconciliation efforts, and prevent product and operational waste.

With the right technology that connects the clinical trial supply chain stages and facilities, providing intelligence throughout the process, you have a successful, comprehensive, end-to-end solution that saves money and helps get supplies to sites at the right time. Then, you can ensure that the investigational product gets to the patient in order to determine the ultimate goal—whether a compound is efficacious. Only then will companies achieve their goals of reducing time to market, shortening study timelines and reducing R&D costs.

Learn more or get started with a real-time pilot.

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About Controlant

Controlant is an ISO 9001:2015 company, headquartered in Reykjavik, Iceland with operations in San Francisco, US, and Dublin, Ireland. We deliver product quality, compliance, and stakeholder value through our unique services-based technology partnership.

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