Article

Reducing Waste with Intelligent Automation Accelerates Clinical Trial Success

Pharmaceutical outsourcing: By Stefan Duerr, Sr. Director, Head of the Cenduit Drug Supply Center of Excellence — IQVIA

Although clinical trials are advancing the development of novel treatments, a lack of robust supply chain management is hindering clinical trial success. With a median waste level of 50% for Investigational Medicinal Product (IMP) kits across clinical trials, supply chain management stands to greatly benefit from optimization delivered by automation and integrated data strategies. Waste in clinical trials can stem from temperature excursions, poor forecasting, data bottlenecks, or inadequate inventory management. These incidents lead to increased costs and supply chain delays. Protecting the drug lifecycle and improving accountability requires a serious examination of robust automation capabilities within clinical trial operations.

New drug developments, such as gene and cell therapies introduce additional complexities in clinical trial operations. The cost increments and difficulty in producing these novel therapies lead to quicker expiration dates, risking wasted Investigational Products (IP). A recent survey shows that the majority of senior clinical drug supply leaders lacked confidence in their ability to supply clinical trials for cell and gene therapies. Due to the increased investment in these novel therapies, and elevated safety concerns that require specialized monitoring, these therapies run a greater risk of incurred costs when excursions occur. Novel therapies introduce greater concerns regarding temperature excursions, and constant evaluation is required to ensure that quarantining and delays are not incurred.

Increased waste across the clinical trial supply chain and lack of confidence in supply chain operations can be detrimental to study outcomes. This can affect the

overall budget of clinical research and lead to trial delays and potential research termination. Clinical trial delays significantly hinder the pace of medical innovation, impacting patient outcomes. Ensuring the safe and timely delivery of IMP is critical to supporting clinical trial success and the improvement of patient outcomes.

Optimizing supply chains with intelligent automation

These challenges underscore the need for improved support of supply chain management to better monitor and track excursions that might compromise patient safety and the efficiency of the drug. Employing new technologies to access real-time data integrations and improved oversight for temperature excursion management is essential to cutting down on IP waste. Leveraging Machine Learning (ML) in the drug reconciliation process is an essential component of improving remote monitoring.

For instance, utilizing state-of-the-art temperature loggers provides end-to-end monitoring for improved drug accountability. The use of automated temperature excursion management is critical to de-risking the supply chain. The use of novel therapeutics requires sophisticated trackers that register even the slightest of changes. This demands the ability to compile data from multiple-minute excursions to evaluate a drug's viability. Through a continuous flow of information across temperature loggers, organizations can improve end-to-end accountability and ensure quality data and regulatory compliance.

By integrating optimized algorithms available through Interactive Response Technology (IRT), clinical product supply chain managers can better predict expiration dates and access real-time simulations to mitigate waste. Intelligent automation paired with advanced algorithms and comprehensive IRT tools leverages an extensive, complex data library to automate and optimize supply strategy for future supply chain events or disruptions. The technologies allow for the continuous and automatic updating of buffer stock levels based on patient status at the site.

Understanding the advantages of reduced waste

Research indicates that pharmaceutical companies spending $10 billion a year on research and development could benefit from $100 million or more in improving their waste performance. Advanced automation leads to significant cost reductions, positively impacting the bottom line. Reduced waste from temperature excursions and expired treatments, lower shipping and storage costs, and decreased labor costs associated with manual inventory management all contribute to decreasing additional operational costs. Improved supply chain management benefits patient outcomes and contributes to the financial success of the clinical trial.

Optimizing drug supply with advanced technology and automating the optimization of resupply strategies based on real-time data, reduces the risk of stockouts, overall costs of drug overage and shipments, and waste associated with shipping and supply strategy management. At the same time, it also reduces manual oversight and enhances patient safety. Beyond cost reduction and waste elimination, this technology aligns with long-term corporate goals of improving sustainability in clinical trials. Prioritizing drug accountability with advanced technologies like ML is critical to decreasing clinical trial waste and improving therapeutic success.

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Stefan Duerr has worked in IRT for 17 years and has been with Cenduit IRT, an IQVIA business, since its inception in 2007. He has worked in various project management roles including leading the global project management team at Cenduit. Stefan currently is responsible for client delivery of key customer accounts and heads the Cenduit drug supply center of excellence. He is very passionate about finding innovative solutions for clinical supply challenges. Stefan holds a Master of Science in molecular biology and an international executive MBA from the University of St. Gallen.

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