Level Up Your Supply Chain Initiatives

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The modern clinical trial landscape is evolving rapidly, with precision medicine leading the way in curing many heretofore untreatable diseases and conditions. As new biologics and cell and gene therapies are investigated and brought to market through clinical trials, innovative manufacturing techniques are required to develop and safely deliver these medicines. However, shipping and storing these treatments is delicate, and wasted IP is costly. Fortunately, new data accountability technologies are available to alleviate participant and site burdens, making it easier for people to participate in trials and simpler for sites to execute trials and collect quality data.

As companies pioneer emerging therapeutic options such as personalized medicine, they rely on these new technologies to collect vast amounts of diverse data and corresponding endpoints spanning trial sites across the globe. Given the complexities of supply chain logistics and clinical trial data management, robust interactive response technology (IRT) providing a detailed drug accountability program is paramount. Drug accountability and management is a mission-critical aspect of any clinical trial, especially for biopharmaceuticals requiring cold chain management and excursion tracking. Pharmaceutical companies and regulators also need assurance that all necessary information is in the record to meet compliance requirements.

Leveling up supply chain initiatives to ensure accountability, sustainability, and optimized IP management is crucial to meeting these challenges. Fortunately, advancements in drug accountability, wearable devices, and emerging technology such as automation and machine learning can increase supply chain efficiency, capturing real-time factors critical to patient safety and protocol adherence.

How Emerging Therapeutics Affect Drug Accountability

New drug modalities, such as gene and cell therapies, RNA drugs, and complex biologics, are more complicated to produce than traditional drugs, making designing and conducting clinical trials challenging. These therapies are also significantly more expensive to make than conventional drugs, and they often expire quickly, increasing the risk of wasted IP. Wasted stock or stock outs increase the costs of clinical trials and create delays. Also, these drugs often have unique safety concerns that require specialized monitoring and reporting.

Historically, drug accountability has relied on siloed tools such as paper or digital logs that require manual input. Also, this data must be transcribed into other systems and reconciled by site and monitoring teams. For example, when a participant returns their IP to the site, the team has to find their original record, update it, and check if the returned quantity and other details are correct and match the trial's protocol. Next, a monitor follows up to check if the record is verified and complete.

Multiplying these tasks over numerous participants creates a significant time burden. Studies are delayed when drug supply managers rely on manual processes and paperwork to document and reconcile participant and IP data. Delays can lead to CRAs raising queries and sites having to address them in various EDC systems, adding even more time. Given the enormous amount of data that new and emerging therapeutics require, the traditional methods of tracking usage and viability are inadequate for today's drugs.

Likewise, designing and packaging drug kits is intricate and involves multiple vendors for production, shipping, and storage. IP packaging can vary wildly, affecting how the drug is ordered, dispensed, and reconciled. Additionally, each aspect of the kit must be traceable, but tracking and reconciling drug accountability is highly complex. For instance, liquid volume levels must be measured when the kit is returned to the site to check for participant compliance, and sites must be equipped with the appropriate devices to measure these volumes precisely.

Patient Centricity Adds Complexity

Paralleling the rise of cutting-edge drug modalities is the rapid evolution of personal technology. Remote healthcare and wearable devices have opened the door to greater patient centricity. However, the increase in DCTs and other remote technologies means more participants are administering trial medications at home or with an off-site HCP. Although this makes participants' lives easier, it creates unique challenges to packaging, delivering, and tracking drug kits.

For example, if a participant receives an injectable drug, they must destroy the syringe safely rather than returning it to the site. In that case, the investigator needs a remote method to prove that the drug was taken, such as visual confirmation with a photo or video call or an auto-tracking device. Given these logistical hurdles, companies are looking for opportunities to simplify operations. With the right technology, companies can de-risk certain areas of the supply chain, fully optimizing shipping frequency to reduce wasted IP and save costs.

Integrating supply chain operations also improves patient care. When systems are fully integrated, the participant follows a seamless journey through the trial's protocol because investigators can accurately dispense randomization and visits. For instance, if a participant is entered into an eConsent system, they can automatically be integrated into an IRT to be randomized. Similarly, data collected directly from patients with an eCOA system provides information that helps better distribute information and forecast future needs. Therefore, optimizing the supply chain improves patients' lives.

Cutting-Edge Solutions For Lifesaving Drugs

IP is wasted when the drug loses viability due to a temperature excursion or having too much supply with short expiration periods that never make it to participants on time. Cold chain storage is vital to preserving drug viability, but temperature control isn't enough to meet regulations. The drug's temperature also must be constantly monitored and reported to maintain its safety and efficacy. Clinical supply managers need continuous information on all temperature excursions and storage activities, including if a drug never leaves storage and expires before use.

Although focusing on patient centricity can add complications, it also provides opportunities when the right technology is engaged. Dedicated apps such as IQVIA Cenduit's Mobile IP enable real-time data collection and ensure the precise IP kit goes to the right participant at the correct time, improving patient care. By persistently monitoring inventory levels and locations, mobile solutions help companies optimize inventory efficiency. The Mobile IP app also increases collaboration and engagement between the site and the monitor remotely or on-site. With data stored centrally through an IRT, creating a digital accountability record that's central and accessible to the entire study team streamlines processes and reduces labor.

AI and machine learning also show great potential for streamlining supply chains for clinical trials. These tools empower supply chain professionals to make data-informed decisions, automate repetitive tasks, identify patterns, and anticipate site resupply needs. Additionally, AI and machine learning have the potential to shorten clinical drug supply timelines by pinpointing potential sources of delay.

Conclusion

As the science behind emerging therapeutics evolves, pharmaceutical and biotech companies need equally innovative solutions to streamline their supply chain logistics and ensure the drugs they need for clinical trials are available, viable, and traceable. Electronic drug accountability systems, wearable devices, mobile monitoring, AI, and machine learning provide myriad solutions to complex problems. If your clinical trials produce 21st-century medicines, then your supply chain logistics shouldn't be stuck in the 20th century. When optimization technology evolves and adapts as rapidly as pharmaceutical science, drug development becomes faster, safer, and more reliable.

About the Author

Maxime has over 17 years' experience in eClinical system design and operations management. 11 of which being in the IRT space. Lately, he has focused on delivering new innovative solutions for IRT and end-to-end solutions to enable an optimized and automated drug accountability process in IRT with the use of mobile technologies. In his current role, Maxime is working on IRT technology solutions with the aim to support decentralized and human centric clinical trials by standardizing Cenduit IRT communications capabilities and system configurability. Maxime holds a Master's Degree in Computer Science from "Conservatoire National des Arts et Métiers (CNAM)" in France.

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