Article

Reducing Costs and Accelerating Time-to-Market for Medical Devices with IRT

Medical product outsourcing: By Kevin Landells, Vice President and General Manager, IQVIA IRT

The journey to bring a medical device to market is filled with high stakes and even higher costs. With clinical trials averaging $31 million for devices under the 510(k) pathway and skyrocketing to $94 million for premarket approval the pressure to find smarter, more cost-effective solutions has never been greater.

The challenge goes beyond financials — each device, ranging from cardiovascular devices to spinal instrumentation to knee advancements, necessitates highly personalized modifications and unique clinical trial parameters. As the landscape for medical devices becomes more sophisticated, so must the technologies that support their development.

In traditional drug studies, sponsors are concerned with material expiration and accurate demand forecasting. However, medical device trials present additional complexities due to factors such as unpredictable patient enrollment, critical device implantation, and potential device modifications.

Medical device clinical trials also present challenges in sample size calculations as participant groups tend to be much smaller. As opposed to drug trials, the select number of patients available for participation adds additional layers of complexity. Medical device studies can be challenging to randomize, especially since they frequently require specific device sizing and modifications.

Additional factors such as evolving regulations and diverse physician techniques compound the challenges in medical device trials. Given the differing regulatory landscapes and standards, sponsors conducting medical device studies must maintain detailed device history records to ensure compliance and traceability.

These challenges create highly nuanced and complex clinical trials. Complications with patient enrollment, device modifications, or additional regulations can lead to unintended delays in trial timelines. Adjustments due to device complications often require additional or ancillary resources, personal, or equipment. These alterations can incur unintended expenses and increase the overall cost of clinical trials.

Adopting interactive response technology in medical device trials

To avoid these repercussions, clinical trial stakeholders are turning to integrative technology to predict and prevent challenges associated with medical device studies. For example, Interactive Response Technology (IRT) offers a powerful tool to mitigate these costs by optimizing clinical trial supplies and device delivery. While IRT has been widely adopted in the pharmaceutical industry for decades, its adoption in the medical device space has been slower, however, its benefits are just as significant.

IRT addresses supply chain complexity, device-specific regulations, and diverse patient populations by enabling real-time tracking of devices, dynamic distribution based on demand, and efficient inventory management. IRT delivers significant savings by ensuring accurate device tracking and distribution and mitigates risks associated with device shortages or incorrect sizing, ultimately accelerating time-to-market. Specifically, IRT addresses the following:

Navigating trial complexities with agile IRT

Medical device studies demand an IRT system capable of efficiently addressing the unique challenges and intricate requirements inherent in such trials.

Real-time device tracking and efficiency

The high cost of medical devices often necessitates frequent relocation. An integrated IRT system can effectively monitor device movement, reducing time and costs associated with redistribution due to sizing errors or patient ineligibility.

Dynamic distribution and cost-effective supply chain

Given the expense and limited supply of medical devices, just-in-time labeling is frequently required. A cost-effective IRT system can optimize your supply chain to meet distribution demands efficiently. Supply chain expertise can provide the necessary capabilities to address these unique challenges.

IRT offers a powerful solution for enhancing the efficiency and effectiveness of medical device clinical trials. By enabling real-time tracking and management of medical devices, this technology ensures that devices are delivered to the right patients at the right time, reducing the risk of shortages or delays. This not only improves patient safety but also accelerates time-to-market.

Furthermore, IRT's ability to automate manual processes, such as randomization, inventory management, and supply chain logistics, leads to increased efficiency and reduced operational costs. By ensuring accurate data collection and reporting, IRT contributes to more reliable trial results.

IRT's ability to track devices in real-time, dynamically adjust distribution and efficiently manage inventory is particularly valuable in the complex landscape of medical device trials. By mitigating risks associated with device shortages or incorrect sizing, IRT helps to reduce costs and delays. Moreover, IRT's automation capabilities streamline processes, enhancing efficiency and overall trial management.

IRT presents a compelling solution to address the challenges and costs associated with medical device clinical trials. By leveraging IRT's capabilities, stakeholders can not only optimize supply chains but also ensure that patients receive the right devices at the right time, improving their safety and well-being. This technology allows clinical teams to focus on what truly matters — bringing life-changing innovations to the people who need them most — while accelerating the path to market for groundbreaking medical devices.

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