How To Reduce Clinical Supply Expense Using An IRT System

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A lack of oversight in managing clinical supplies can threaten study outcomes, bring studies to a halt, and even jeopardize a clinical research program. Meanwhile, clinical supply and clinical operations teams frequently handle several studies simultaneously, all of which have many moving parts requiring high attention to detail. Without a solid supply plan in place, this can be a recipe for disaster. This article outlines key components of a solid clinical supply management program, defines interactive response technology (IRT) and its role in clinical supply management, and explains how implementing an IRT system can reduce clinical supply risks and costs.

The Nuts And Bolts Of Clinical Supply Management

Before technology can help a sponsor manage its clinical supplies, a foundation of good practices and procedures must be put in place and executed regularly. When not managed correctly, clinical supplies can be the source of increased risk to the trial as well as escalating costs to the sponsor company. For a sponsor to accomplish successful clinical trials, it will need a solid program for managing its materials, supplies, and doses. This involves understanding the protocol, inventory, destinations, regulations of those destinations, methods of shipping, and number of enrolled patients and then adequately planning for it. As background, supply chain management plans should take the following into consideration:

- A lengthy amount of planning time — typically six months or more for global studies — for forecasting inventory needs, filing for import licenses, and additional preclinical activities.
- International shipping regulations and language and labeling requirements need to be evaluated and understood. This planning should also make contingencies for adding countries mid-study.
- Constant and reliable communication between operations and supply teams.
- Finding the balance between being economical and wasteful. Not having enough supplies and doses for patients is detrimental, but so is having too many.
- Avoiding unnecessary risks and accounting for the unexpected with contingency plans.
- Forming partnerships and collaborations with consultant groups. They often have knowledge and expertise that many, especially smaller, sponsor companies don't have in the clinical supply chain.
- Frequent review forecasted data, timelines, and inventory and make adjustments as needed.

Planning out the clinical supply chain, as well as its timeline, can be incredibly challenging as all data for it are in the form of estimates. For instance, it can be estimated that 10 sites will have 100 patients. From there, buffers and overages are calculated to ensure enough inventory is available for the entire study. But what if the estimate of 10 sites and 100 patients doubles? What if it's cut in half? As clinical trials are always evolving, a most-up-to-date estimate should be used to eliminate shortage or overage.

IRT Systems And How They Aid In Clinical Supply Management

Sponsors looking to get the most out of their clinical research and development use IRT systems to manage their trials, supplies, and data. These software systems have been used for nearly 30 years, first using touch-tone telephones and fax machines for database input and retrieval. In recent years, web-based technology has evolved as the standard platform. And as clinical trials have become more complex, so has IRT and its capabilities.

Modern IRT systems bridge patient drug assignment, inventory, and resupply management. They also connect supply and clinical teams to help find the best balance of both teams' needs. These systems help clinical trials and supply management in several ways. IRT helps manage the randomization of patients and the dispensation of products to them to preserve unbiased results of the trial through predetermined patient demographics within the system. Inventory management is preprogrammed into the system based on the sponsor's needs.

When dispensing occurs, the system determines the correct drug/placebo and the dose based on the randomization list and site inventory. The system is also able to communicate with the site's depot or distribution company regarding which drugs go to what sites and when those drugs are needed. For instance, if a patient visits the site once per week, the IRT will place orders for that patient's dosage as needed based on preprogrammed criteria.

As each clinical trial is designed differently, an IRT system is designed to manage and meet the needs of a single, unique trial's protocol. Essentially, how the sponsor says it will conduct a trial is how the IRT is set up; the IRT identically matches the trial protocol. This includes which countries are involved in the trial, how many patients are anticipated to be in the trial, the type of drugs the trial will use, how frequently doses will be given, where the doses will be given, and which depots will be used, among a host of other criteria and variables. Additionally, IRT systems can also manage temperature excursion and accountability. These were once paper-based, manual activities, but are now an integral and automated aspect of IRT designed to save time and money.

What About Costs?

IRT systems have become more affordable, ranging anywhere from $50,000 to $300,00 depending on the phase of the study, while becoming more feature-rich and customizable. Lowered cost of investment coupled with greater features means the technology can be used by any size sponsor for any size trial.

But clinical trials and bringing a drug to market are incredibly expensive, often costing in the tens of millions of dollars. And data management accounts for a significant portion of that total cost. Even though trial costs dwarf the cost of investment in IRT, the investment is still significant and needs to be recouped. That return on investment can be immediately found in the data — required for submission to regulatory bodies in order to bring the drug from trial to market — the system collects. An effective IRT system for managing clinical supply data can mitigate costs while capturing a trial's necessary data, maintaining data integrity, and aiding in bringing the drug from trial to market faster.

Further, the risk of human error in data collection and transfers is significantly diminished through IRT. If a system is set to generate results and data automatically, the human element is almost entirely removed, nearly eliminating the chance for errors. If all of IRT's capabilities were completed manually, it would take a huge workforce, consuming many hours at a significant cost, and would contain a lot more errors compared to IRT doing the same work. Error-loaded data can put your whole trial at risk. A clinical trial needs to ensure that a diverse population of subjects are involved in the trial. It is a sponsor's responsibility to provide evidence that the trial tested for and was successful for what was laid out in the protocol without bias. Errors in this data or "proof" could lead to a failed submission.

In addition to secure data management, IRT benefits clinical supply management through automated initial shipments activated by site activity, automated resupply capabilities for both sites and depots, the ability to track and manage product expiration dates and retest dates, do-not-dispense and recall capabilities, and real-time reporting.

Planning For, Implementing, And Using IRT

When IRT is brought into the early phases of trial planning, the software provider is put in the optimal position to create a system that best supports the trial design. This way, the solutions provider can fully grasp the trial protocol and design accordingly. The provider can apply their knowledge, experience, and lessons learned to avoid obstacles the sponsor may not be aware of or may have overlooked. Further, the expertise and advice of the IRT provider often proves beneficial for small sponsors without a dedicated supply chain team.

Ideally, sites should provide the input needed to design IRT because of their hands-on use of the technology and understanding of trial needs. The clinical supply manager's input regarding supplies, labeling, and depots is also crucial for IRT planning and design. Many sponsor companies request demos of systems to understand how they will work in a mock environment nearly identical to what is required. If the sponsor is satisfied with an IRT proposal based on the mock environment, further discussions with the vendor will revolve around specification — how to precisely build the software so all parties can operate it and be on the same page throughout the trial. After specification is finalized, programming and testing continues based on documentation.

The time from conception to launch varies depending on what type of customization the system requires and on testing results. But generally, the timeframe is anywhere from two to 12 weeks. Sponsors looking to invest in IRT should pause and think about their current needs, their upcoming studies and their corresponding needs, as well as the timeframes required to complete them. For instance, they could review their quarterly schedule of studies and request proposals for each in their chronological timeline.

Once an IRT system has been designed, tested, and launched, users must be trained to operate and utilize it to its maximum potential. Most IRT systems have been reviewed by end users during the proposal and testing phases, so systems are already intuitive and user-friendly. User manuals, for the most part, can guide users through IRT systems and provide troubleshooting procedures. However, sometimes additional training may be required and can be provided internally or through the vendor.

IRT has been preprogrammed to fit all the needs of the trial, but this doesn't mean it's a "set-it-and-forget-it" technology or approach. The system is completely automated, yes, but it must be overseen to further reduce errors. This is where self-service functions come into play. With self-service, users with proper credentials (as determined in the proposal and protocol) are able to enter the system and update a number of different criteria, including, but not limited to, adjusting site-level supplies based on actual enrollment, transferring supplies amongst depots, adding depots and countries to a study, making label changes, updating resupply strategies, and quarantining supplies should they become compromised. In older, less-flexible IRT systems, these types of changes would require a phone call or email to a help desk, and there would be a 24- to 48-hour waiting period for updates to take effect. In a worst-case scenario, a change order would be required, furthering costs and demands on time. Now, role-based permissions are agreed upon at study design to ensure the right people are making updates. Qualified users are able to log in to the system from anywhere to update fields and make immediate changes when needed.

IRT allows sponsors to manage multiple, complex clinical studies simultaneously. These systems come with many capabilities to help trials and their associated supply chains run more smoothly. As trials and supply chain management become more complex, the capabilities of IRT will continue to expand. However, sometimes the industry overcomplicates things despite the simplest solution often being the best one. Just because the technology, or a feature of it, is available doesn't mean it's needed. Sponsors looking to invest in IRT should understand that not all IRT systems are created the same. Sponsors should know their outcomes and what questions to ask when searching for and implementing IRT to find the solution that works best for them and the needs of their trial.

About The Author

Korinne D'Orsi is associate director of clinical supplies for YPrime, where she leads efforts to help biopharmaceutical companies with clinical supplies forecasting, demand planning, and global distribution strategies. D'Orsi has more than a decade of experience with strategic supply chain planning, team leadership, and process improvement initiatives.

D'Orsi previously served as manager of global clinical supplies for PPD. There, she held responsibility for project and team oversight of clinical trials that typically involved tens of thousands of patients and hundreds of investigator sites around the world. Prior to PPD, she was director of global project excellence for Marken, a global provider of clinical trial logistics solutions.

About YPrime

With more than a decade of focused work with eclinical systems, YPrime is a provider of technology and services that expedite clinical trial data management. Cloud-based interactive response technology (IRT) and electronic clinical outcome assessment (eCOA) platforms enable greater speed, precision, and integration in clinical trial management. YPrime's technology and service offerings enable sponsors to move faster and more efficiently to their next development milestone.