Clinical Trial Prescription Services: Navigating Sourcing in an Ever-Changing World

The key benefits of a pharmacy dispensing process as a solution for decentralized trials.

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The process of sourcing the necessary drugs for clinical trials is expensive and prone to waste. Our clinical trial prescription service can streamline the process, while saving time and money.

The clinical trials arena is being affected by several trends that are spurring developers to adapt their clinical supplies strategy.

- **Patient centricity** is a key trend, with many sponsors now viewing patients as collaborators who are core to the overall success of a clinical trial.
- **Decentralized trials** and **direct patient models** are fairly new on the scene and COVID-19 has accelerated the adoption of these approaches. The largest global contract research organizations (CROs) have been adjusting their business models to fully support and integrate decentralized trials into their processes. Several of them have acquired nursing companies for partnerships that facilitate the more patient-centric model. From a clinical supplies perspective, a major focus in decentralized trials is home deliveries and convenience for patients as part of their engagement in a clinical trial.
- The **costs** associated with bringing a new drug to market are widely acknowledged; reduction of waste and costs are always concerns. Clinical supplies for open-label oncology trials generally involve a huge amount of cost for the comparator, the standard of care, or the combination medication. Purchasing models are changing to address these costs. The days of the

straight-comparison purchase directly from a manufacturer with 30% overage are ending. Sponsors are looking for a much more efficient supply chain and more streamlined access to drugs by different mechanisms compared with the traditional source, pack, label and site distribution model.

- **Shortened timelines** are another key current trend. As an example, several large pharmaceutical companies have established company-wide objectives to reduce clinical trials startup time by 50% per category over the next two years. From a supplies perspective, this could mean getting away from a three- to four-month lead time with the contract manufacturing organization (CMO), as well as providing prescriptions on a real-time basis.
- Last, we are increasingly seeing **limited distribution status** of the new standard of care medications in the United States and Canada, which means they are only available through prescription and not by traditional wholesale routes. In some cases, entire trial lines cannot be run unless there is a different mechanism to access these medications.

HOW A CLINICAL TRIAL PRESCRIPTION SERVICE CAN HELP

With all of these challenges, a pharmacy benefit card specifically for clinical trials can help. For instance, the Myonex Clinical Trial Prescription (CTRx) card gives patients access to drugs and supplies (e.g., standard of care, combination and rescue medications as well as ancillary supplies) directly through a broad pharmacy and specialty pharmacy network, with no payment due from the patient or the pharmacy. Flexible dispensing options can be set up, depending on the trial whereby a single, large or specialty pharmacy can be leveraged to ship the drug product to the site or directly to the patient. Clinical outpatient sites can also be used to dispense the drug. The card can be used for U.S. and Canada open-label drug supply, investigational medicinal products and non-investigational medicinal product.

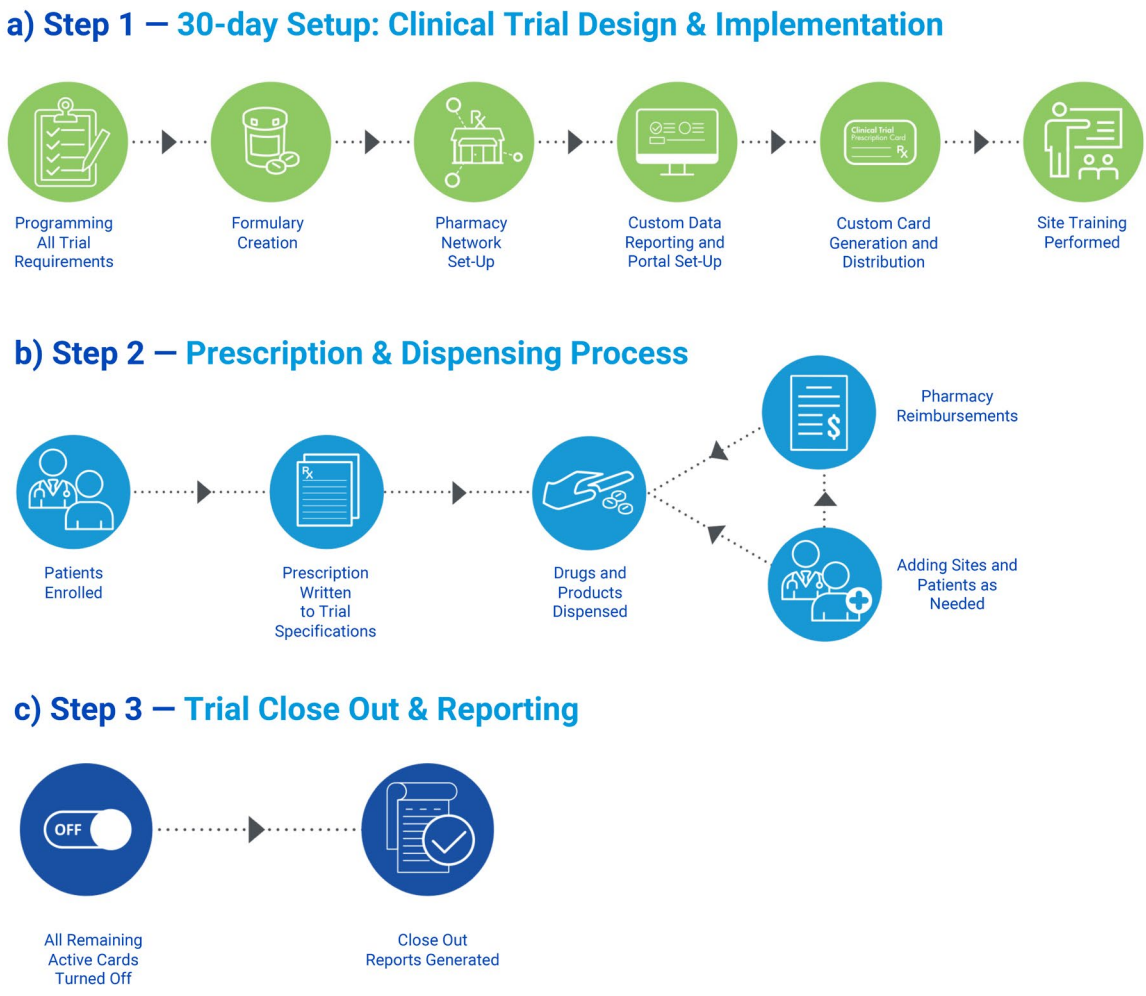
"With all of these challenges, a pharmacy benefit card specifically for clinical trials can help." —Andrew Gregoire, Vice President of Business Development, Myonex

Immediate benefits of these alternative prescription methods are waste reduction and cost savings. Trials often factor as much as 50% overage into their cost estimates. At the end of the trial, any unused overage becomes waste.

A prescription services approach also enables fast startup by reducing the time for packaging and labeling activities. Detailed planning, forecasting and inventory management are eliminated, as well as expiry data tracking.

Access to specialty drug products can be difficult for a trial, and a prescription service may be able to help. Myonex's CTRx service has access to every specialty drug product

Figure 1: Process for using Myonex's Clinical Trial Prescription (CTRx) card.



commercially available in the United States and Canada.

A prescription service also eliminates the need for sites to worry about sourcing or waiting to be reimbursed by sponsors. They don't have to go through pharmacy benefit plans or prior authorizations in processing patients' insurance.

A prescription service can streamline many aspects of getting the necessary drugs to patients who are enrolled in clinical trials, including flexible options for receiving the medications, whether that be at their local pharmacy or delivered directly.

The process is described in FIGURE 1, where FIGURE 1a illustrates the first steps for trial design and implementation from programming the clinical trial requirements through card generation/distribution and site training. FIGURE 1b shows the setup of the prescription and dispensing process. The formulary design will help determine whether the trial will be utilizing a central pharmacy or

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specialty pharmacy shipping directly to the clinical sites or directly to the patient. Myonex's program includes an online portal that provides easy access to claims and reporting information. The company also provides training for every site that uses the CTRx, helping to enroll patients and get them set up to receive medications on time. It's important to note that while CTRx is newer for clinical trials, it is not new to healthcare. Most clinical sites are familiar with pharmacy benefit programs and how they fit in the enrollment process.

Moreover, several real-life trials have already benefited from the CTRx program.

CASE STUDY 1: ACCESS TO LIMITED DISTRIBUTION DRUG

A drug specified by the sponsor was unavailable for purchase due to a limited distribution designation. The sponsor had tried to acquire the drug directly from the U.S. manufacturer, which kept the product under tight control. The sponsor was told, "There are other mechanisms in place for patients to receive this product."

The impact was that the sponsor was conducting a three-arm trial without enrolling a single patient in this particular treatment arm for an entire year.

A prescription drug service was ultimately able get the sponsor access to the drug via a specialty pharmacy partner. The drug could be shipped directly to the clinical site, enabling patients to enroll in the third arm and move forward.

A solution that many sponsors have used in the past to gain access to these limited drugs is to have the sites source the drug products and then the sponsors reimburse the sites directly. That model is typically more expensive than a prescription drug service, which may have pre-negotiated pharmacy rates that are 10–20% lower than what the sites might charge.

CASE STUDY 2: ACCESS TO DRUG WITH RESTRICTED ALLOCATION

The second trial was an ongoing project for several years in which Myonex supplied a few thousand packs of Ventolin (albuterol) every quarter to the client. This inhaled medication is typically used to treat asthma or bronchospasms. In the trial, it was being used in a combination therapy. When the pandemic hit, Ventolin was used to treat COVID-positive patients. Manufacturers placed the product on restricted allocation, which meant that large supplies for use in clinical trials could no longer be sourced. This put the entire trial in jeopardy. Nonetheless, with CTRx, the sourcing was quickly shifted to Myonex's network of 65,000 local pharmacies, which usually have Ventolin on hand, and the trial was able to proceed.

CASE 3: COST SAVINGS

The third example was a global Phase III trial using Keytruda (pembrodizumab) in combination with the sponsor's own investigational product. The trial involved 200 U.S. patients at 25 sites. The sponsor, in conjunction with its CMO, had planned for a 30% overage of Keytruda, which is equivalent to about 1,500 vials or $6.5 million in drug cost (not including the full GMP pack, label, release and management process). With CTRx, this study saved about $6.5 million right off the bat. Sites are invoiced monthly as patients enroll. This type of scenario is particularly impactful with high-value drugs and short expiry dates like Keytruda, which expires in 13–14 months. These drug acquisition processes can save even more with newer therapies that might cost $10,000–$30,000 per dose. With the traditional amounts of waste, trials involving these medications can amass overages in the tens of billions of dollars.

CASE 4: PHASE IV DTP

In the next real-life example, the sponsor company wanted to conduct a Phase IV pragmatic or real-world evidence study using their own commercially approved drug product. The solution they were gravitating toward originally was to store the drug at a local depot and ship via specialty carrier directly to the patients. With this program, several thousand enrolled patients would receive monthly doses over a four-year period of time. The overall number of shipments that this approach would require was well over 100,000, with significant costs in logistics and inventory management.

In contrast, Myonex was able to create a network made up of a combination of retail pharmacies and a ship-to-patient option from a central pharmacy. The cost savings in logistics alone was $20 million. A prescription-

Figure 2: Examples of trials that would benefit from CTRx.

based supply model can be ideal for any open-label trial design requiring commercial medications or any trial that needs to get started very quickly. CTRx, for example, can start up a study in as little as 30 days in the U.S. and 60 days in Canada by eliminating packaging and labeling activities. Moreover, the clinical supplies team can be freed up to focus on other aspects of the trial.


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SUMMARY

FIGURE 2 lists the types of trials for which the CTRx service is ideal. Any trial in which direct shipments to patients are involved can benefit from a prescription service, as can any trial involving a high-value drug, especially if the expiry is relatively short. A prescription service like Myonex's Clinical Trial Prescription Service can cut costs and speed up the implementation of trials. Sites no longer need to worry about sourcing drug products or waiting for reimbursement. Used in conjunction with Myonex's global sourcing and distribution strategies, the CTRx card removes the time, cost and inconvenience factors that have been characteristic of clinical trials.

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