SIGNANT HEALTH
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The Signal

Direct-to-Patient Clinical Supply Distribution: Everything You Need to Know

The adoption of decentralized studies has rapidly increased thanks in part to the recent pandemic, which encouraged regulators to permit more flexibility within protocols and forced sponsors to implement strategies that maintained their research continuity. Traditionally, the industry focuses on modifying existing patient technologies, such as eCOA, to support remote trials. However, this overlooks a crucial component to a study's success: clinical supply chain management. Today's direct-to-patient (DtP) approach revolutionizes this key study component making the clinical supply chain part of the patient experience for the first time.

Delivering clinical supplies to locations outside of investigator sites on time is no easy feat though, especially when decentralized studies are at a global scale and treatments have special requirements.

Partial or fully remote studies could benefit from adopting a DtP approach. The home delivery does more than just ensure patients have continued access to treatment. We take a closer look at the top three reasons why sponsors should consider DtP.

Reasons to Adopt a Direct-to-Patient Approach

1. **Access dispersed patient populations**

   DtP allows you to access patients who may not live close enough to a clinic and would otherwise not be able to participate. By bringing therapies directly into patient homes, sponsors can reach a broader, more diverse patient pool. Previous factors such as location, lack of transportation, travel expenses, and symptoms that affect a patient's mobility will no longer deter patients from participating in a clinical trial.

2. **Offer a patient-centric approach**

   Participant fatigue and dropout often occurs when the study becomes too burdensome for participants or their caregivers. A DtP approach improves the clinical trial experience by offering conveniences that previously did not exist in clinical research.

3. **Optimize supplies to cut costs**

   Historically, the primary goal for a study's clinical supply chain was to ensure that enough

supplies were available at sites to safeguard against potential changes or issues. DtP is a more efficient way to run a trial as it doesn't require excess supplies to sit at sites. A much smaller stock can be maintained at a single depot, which effectively pools the supplies and reduces drug wastage.

Types of Direct-to-Patient Distribution Models

Once you decide to adopt a DtP approach, you'll need to decide which model best fits your specific study.

Depot to Site to Patient

Patients are allocated investigational products from the site's inventory during a study visit. Delivery logistics to transport the medication to the patients' home are handled by the site or local pharmacy.

Depot to Patient

Depot to patient models deliver medication from a central warehouse direct to patients. It may be the same depot that supplies sites, but it also may be a specialized, central pharmacy. Keep in mind that companies must adhere to local regulations and investigator oversight is required for any depensation of study medication.

Benefits of Depot to Patient

- Storing supplies at a central warehouse increases visibility and control.
- Advanced algorithms prevent overstock.

Special Considerations for Direct-to-Patient Models

It's best for sponsors to decide on a DtP approach before the study protocol to enable sites and countries to easily opt in later without numerous regulation and requirement complications.

Before selecting a DtP model, sponsors should consider their study's variables, such as the administration route, medication temperature requirements, and reconciliation process.

The importance of DtP makes it crucial that sponsors and distribution partners have a well-defined, optimized execution plan. This not only includes how they'll get drugs and supplies to the patients' homes, but also supporting the returns process – from reconciliation to destruction.

You may still want to offer patients and/or investigators the option to pick up supplies at the clinic.

Finally, DtP requires an RTSM solution to create different models to replace the traditional site ordering.

How RTSM Helps Direct-to-Patient Distribution

Capable of handling the complexity of decentralized distribution, Signant's Randomization and Trial Supply Management (RTSM) solution dramatically streamlines the shipment process. In fact, the solution's innovative resupply algorithms were designed specifically to optimize supplies and may be applied for DtP scenarios, such as patient specific ordering. Shipments can be generated automatically or manually based on your preferences. Inventory can be managed on all levels to effectively mitigate DCT supply chain risks.

RTSM also protects patient privacy and supply chain integrity by managing unblinding scenarios and factors that could significantly impact the clinical supply chain (timing, shelf life, and temperature). Its advanced inventory management capabilities can even support various DtP shipping models within a single study.

Best of all, the solution is supported by an experienced team who understands the challenges of DtP models and helps you mitigate unexpected challenges.

Need help implementing a DtP model in your next study? Contact our team today. We'll make recommendations, get you set up, and answer any questions.

Signant Health

Signant Health is the evidence generation company. We are focused on leveraging software, deep therapeutic and scientific knowledge, and operational expertise to consistently generate quality evidence for clinical studies across traditional, virtual, and hybrid trial models. For more than 20 years, over 400 sponsors and CROs of all sizes – including all of Top 20 pharma – have trusted Signant Health solutions for remote and site-based eCOA, eConsent, IRT, supply chain management, and data quality analytics.