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Water Cooler Chat

Rapidly Switching to Direct-to-Patient Protocols

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THE BRIDGE BETWEEN LIFE-CHANGING THERAPIES AND PATIENTS

PCI Clinical Trial Services hosts a weekly Virtual “Water Cooler” Chat series, where our subject matter experts host informal discussions around a number of clinical supply hot topics.

Rapidly Switching to Direct-to-Patient Protocols

Rich Nelson, Sr. Manager, Global Logistics recently discussed the factors which need to be considered for clinical trial sponsors to incorporate Direct-To-Patient (DTP) protocols rapidly, to help navigate the challenges presented by the COVID-19 pandemic.

In the midst of the COVID-19 pandemic, clinical trial sponsors are having to quickly find alternative methods to keep their trials moving forward as challenges arise such as clinical sites having to close, or patients being unable to travel to the sites for safety reasons.

To keep clinical trials on track, Direct-To-Patient (DTP) shipments have significantly increased since March 2020. As of April 17, 2020, the FDA is allowing DTP shipments to be used as an alternate distribution method without amending the clinical protocol. If you have questions regarding what exactly is allowed, please contact your local IRB or FDA office and have your regulatory group confirm this before proceeding with Direct-To-Patient shipments.

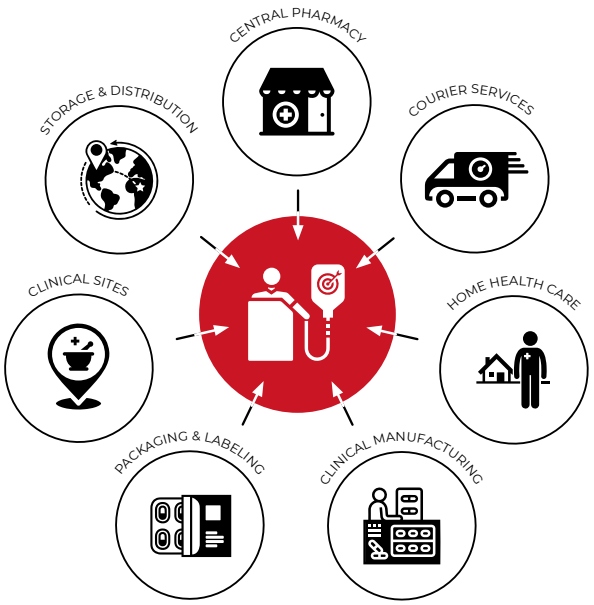
It is important to remember that the term ‘Direct-To-Patient’ can be misleading, as an intermediary stop will always be required for traditional DTP shipments, be it a central pharmacy or a clinical site. For traditional DTP studies, kits can never go directly to patients from a central depot. Therefore, using experienced courier partners is extremely helpful to navigate DTP, especially if a sponsor is switching to the DTP method rapidly.

The State of DTP in the EU and only the EU

On Tuesday April 28, 2020, the EMA issued a new guidance regarding the opportunity of by-passing an investigator site should it be required and having a distribution depot/CMO ship directly. Section 9 discusses “Changes in the distribution of the investigational medicinal products.”

It outlines the expectations for DTP consignments, and also when shipping directly from a depot to a patient may be justified. The depot and the sponsor company would need to establish a process to ensure patient confidentiality, and all GDPR requirements are met throughout the supply chain. Given the current rapid changes of guidelines, please confirm with your regulatory group, or local IRB or FDA office before committing to a protocol change.

Direct to Patient



How does the courier know where to go?
There are two common ways that couriers receive patient shipment information. The first way is for the sponsor company's CRO to send a list of patients in one comprehensive information drop. This allows the courier to pre-scout routes and determine the most efficient delivery paths.

The second (and more common) way is for the clinical site or central pharmacy to provide this information at the time of each shipment, as part of the request to come pick kits up at the site. This method has proven to be faster, as information is being given to couriers on an as-needed basis. This does slow down delivery as the courier company will not have the chance to pre-scout delivery routes, however, the speed of setup is higher for each delivery.

In this COVID-19 situation, how would you handle DTP when the site is closed with no access to trial product?
Consider using a central pharmacy to fill each patient's order. Courier partners can ship to a central pharmacy, who can store the trial product until it needs to be shipped to the patient.

TIP

Use a central pharmacy for DTP if your clinical site is closed with no access to trial product.

This does come with a few considerations, namely that the central pharmacy does not know what to give each patient as they don't have the ability to run the dispensing transaction. You must work with your IRT system to create one of two things:

OPTION 1
Create a new site and assign the patients to the new site.
OPTION 2
Have the investigator from the closed clinical site still run the transaction and communicate that information to the pharmacy. There still needs to be IRT manipulation to have kits from the central pharmacy be assigned to the patients from a different site, as an IRT system will only pick patients from kits of the site the patient belongs to.

What does the actual delivery look like during this time of COVID-19?
Setting up DTP as an alternate shipping method for a clinical trial has several moving parts to consider, namely that the actual handoff and delivery process to the patient needs to be contactless.

The courier will only ever deliver the kit directly to the patient. Traditional DTP would call for home health care to be involved, but due to the COVID pandemic this is not currently possible. At the time of delivery, the courier will call ahead, arrange a delivery time, and execute the delivery in a non-contact, non-interactive manner. The patient will then take the box, keep the clinical kit, and return the box and temperature monitor back to the courier so that the data temperature can be evaluated.

Are there any countries where it would be more difficult to implement DTP due to COVID-19?
As far as we know, any country that does traditional DTP will support the COVID-19 DTP model. While the FDA

is allowing sponsor companies to switch the protocol without making an amendment, it is unclear if other countries are making the same concession.

Each state (in the USA) has its own requirements. Can the central pharmacy ship to any location in the US?
Yes, central pharmacies can ship anywhere; they are licensed to provide to patients regardless of where they live.

How does PCI support the DTP process?
PCI Clinical Trial Services would coordinate the DTP transaction for the sponsor company. A point of contact email would be set up for your clinical site or central pharmacy to notify us when a shipment needs to be done. We would have the parameters of your shipment ready to go at the touch of a button when your shipment needs to be prepared. All your site would have to do is send an email to us and we would work with the courier, and clinical site to get your shipment prepared and delivered.

What if the clinical site doesn't want materials returned, can we ship the material back to the US or must we use a local depot?
Currently, there are no changes as to what is allowable in terms of returns from an import/export regulatory viewpoint. Whatever process is already in place for that country is the process that needs to be followed. So if you are returning materials from South Korea for example, you can ship the material back to the US. However if your trial is in China, the materials can never leave the country, so in that case a local depot would need to be used.

When a courier delivers clinical supplies, how long does it take for the temp data to get back to the sponsor?
If a temperature excursion occurs before the courier has handed the kit off to the patient, the delivery will be rescheduled. The sponsor company and relevant partners (i.e. PCI Clinical Trial Services) would be notified to determine if the material is still usable, or if the patient needs a new kit.

Is the process of DTP in Canada the same as the US?
Yes, as long as a central pharmacy is set up there, otherwise the process of using the clinical site as an intermediary site is a possibility.

Check the Latest Guidelines on Distribution
As the clinical world adapts to this new COVID-19 reality, it is important to operate according to the most current guidelines to ensure your DTP protocol, be it traditional DTP or bypassing the investigator site (the latter of which is currently allowed by the EMA) is executed as needed.

About Rich Nelson, Sr. Manager Global Logistics, PCI Pharma Services

Rich Nelson has over 15 years of clinical and commercial distribution and logistics experience. In his current position at PCI, Rich works with clients to provide seamless global distribution for their investigational drug products, ensuring cost-effective and time-efficient delivery throughout the clinical trials process. Rich has a B.A in Criminal Justice and Law Enforcement from Monmouth University.

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