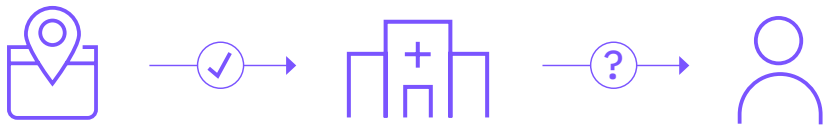
CALYX™

CASE STUDY

Keeping Studies on Track with Direct-to-Patient Shipments



SITUATION

China was the first country affected by COVID-19; thus trial teams, depots, and sites did not have enough time to prepare for it. As a result, we noticed a significant increase in late dispensing visits in studies conducted throughout China. Where Chinese New Year would usually delay visits a couple of weeks, it took 12 weeks to return to an acceptable ratio of late dispensing visits.

When looking at the ratio of late visits in other countries, we did not see the same impact, mainly because sponsors had put mitigating actions in place to keep resupplying patients, even if they could not attend dispensing visits at sites.

Having the ability to ship medication directly to patients was key in reducing the incidence of late dispensing visits as COVID-19 impacted other countries. This enabled sponsors to keep trials on track and ensure patients continued their treatment while staying safe during the pandemic.

INCREASE IN LATE DISPENSING VISITS

The COVID-19 pandemic put a huge amount of pressure on study teams to ensure patients were supplied with the right treatment, even in locations where patients could not attend site visits. At the peak of the pandemic, most trials were affected in one way or another.

The graph below illustrates the impact we saw across all studies run in China on the CALYX Interactive Response Technology (IRT) platform.

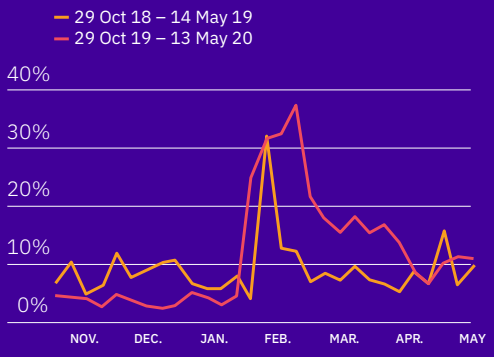


Figure 1. Percentage of scheduled visits recorded late across trials run in China

QUESTIONS RELATED TO DIRECT-TO-PATIENT SHIPMENTS

There are numerous considerations, arising from both regulatory and privacy concerns, when looking at shifting a trial to the patient's home with direct-to-patient (DtP) shipments:

COMPLYING WITH REGULATIONS

- Can patients be treated at home?
- Which countries allow DtP? And under which conditions?
- Who is allowed to dispense medications to patients?

PROTECTING THE PATIENT'S PRIVACY

- How to share the patient's name and address with the logistics provider, but hide it from the sponsor?
- How to keep the patient's participation in the trial confidential?
- How to avoid disclosure of the patient's health data?
- What is a suitable process for DtP shipments including logistics providers, sites, and IRT?

ACTIONS FOR IMPLEMENTATION

There are simple steps that can be taken to alleviate concerns. These include wording in the clinical protocol justifying why direct-to-patient supports the patient's safety and treatment, as well as the process followed for DtP.

Additionally the Informed Consent form should be updated to:

- Include patient information and agreement to send shipments to patient's home
- Include additional data protection clauses, explaining data transfer to external parties, with patient's signature
- Ensure no disclosure of patient's health data and trial participation
- Ensure country-specific rules are followed

RULES TO FOLLOW FOR DTP SHIPMENTS

- The investigator must be involved and informed about each Investigational Medicinal Product (IMP) dispensing to a patient
- A specialized courier must be contracted, offering:
  - > Dedicated processes for DtP shipments
  - > Trained drivers assuring handover to patient
  - > Ability to keep patient data confidential
  - > A clinical supply distribution facility or pharmacy allowed to dispense medication according to local law
- An IRT system issuing dispensing information and including process flows for DtP shipments
- All kits have to be returned to the site responsible for the drug accountability process

Calyx regularly implements Direct-to-Patient solutions in our IRT system. Our IRT dedicated supply chain experts are here to help with any questions related to DtP shipments.

SITE-TO-PATIENT SHIPMENTS

- Calyx IRT does not need much adaptation for site-to- patient shipments. The investigator can perform the dispensing in the system as usual and prepare the kits based on what has been assigned by the system.
- They would book a courier to collect the kits and deliver them to the patient. The courier can then inform the site that the kits have been correctly delivered, which can be recorded in the patient's eCRF.
- We recommend increasing the pack life of the treatment, to take into account the time between the dispensing transaction and when the treatment is handed to the patient.

DEPOT-TO-PATIENT SHIPMENTS

- Depot-to-patient shipments are more complex to set up, as the investigator has to be involved in IMP dispensing.
- The process we recommend is to reserve some of the kits stored at the depot for a specific site. Calyx IRT can accommodate this in the same way as raiding a shipment request to the site.
- When the investigator allocates a kit to the patient, it is assigned from the pool of kits reserved at the depot.
- The depot organizes the courier, who then informs the site once the kits have been delivered to the patient.

How can Calyx IRT automate DtP?

Reserving stocks at the depot

- Calyx IRT can make this process simpler by providing a transaction to the depot staff to ring-fence some of their stocks for a specific site.

Site-to-depot communication

- Calyx IRT generates notifications whenever a kit assignment is performed in the system. By sending an automated notification to the depot, IRT makes the communication between the site and the depot simpler, removing the risk of mistakes in this critical process.

Proof of delivery

- Whenever the courier has delivered kits to the patient, the site needs to be informed that kits have been delivered in good condition. The courier could access Calyx IRT to record this directly in the system, or there could be an integration between the courier and the system to automate even further.

  In both cases, Calyx IRT marks the kits as being used by the patient and integrates it with the eCRF. A notification can also be sent to the investigator, informing them of the delivery and the kit's condition.

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