



# Feasibility of shipping clinical trial drugs directly to patients' homes

## Introduction

Conducting clinical trials for rare, debilitating diseases can be particularly challenging, owing to the smaller patient population with limited mobility and greater caregiving requirements. Direct-to-patient shipping of clinical trial drugs, while not typical, might help to reach these patient populations who otherwise would struggle to participate in and comply with clinical trials. However, implementation of this strategy is challenging because of many reasons such as the logistical considerations and regulatory requirements regarding patient confidentiality and quality control. Recently, Bioclinica collaborated with a sponsor to successfully ship study drugs directly to patients.

## Situation

The clinical trial was evaluating therapy for a rare, debilitating, progressive disease that is characterized by motor, cognitive and behavioral symptoms, with a prevalence of only 5–10 per 100,000. It has a young adult onset and is typically fatal 10–20 years after the symptoms manifest. It can be particularly difficult to leave the home for visits, and patients often requires 24/7 caretaking. Currently, only symptomatic therapy is available.

In this pivotal 12-week, randomized, double-blind, placebo-controlled phase 3 trial in the US and Canada, an updated version of existing therapy for this disease was being evaluated. The 12 weeks consisted to an 8-week titration phase with regular visits and a 4-week maintenance phase, during which the dose could be reduced at any time. Because of the need for close, ongoing monitoring and the limited mobility of this patient population, direct-to-patient shipping was considered as a potentially useful strategy to dispense the medication.

## Solution

To better reach the intended population of patients, Bioclinica collaborated with the sponsor to ship drugs directly from the depot to the US-based patients. For patients in Canada, all drugs were dispensed in the typical manner at the site, due to regulatory restrictions.

To accomplish direct-to-patient shipping, the sponsor first located a depot in the US that specializes in shipping drugs directly to patients. The depot has a pharmacist who prescribes, dispenses and ships the appropriate medication for each patient, according to the study protocol.

MAINTAINING PATIENT BLINDED STATUS

|   |  |  |   |  |
|---|--|--|---|--|
|  <p><b>TRIDENT</b> only stored blinded information that was identified using the subject number.</p> | <p><b>TRIDENT</b> provided the subject and kit numbers to the depot.</p> | <p>The <b>DEPOT</b> was only provided the subject information on the subject contact form.</p> | <p>The <b>DEPOT</b> pharmacist matched subject and kit numbers to kit type and the patient's full name and address.</p> | <p>The <b>DEPOT</b> pharmacist then pulled, packaged and shipped the kits.</p> |
|---|--|--|---|--|



### Direct-to-Patient Shipping Process

Upon site activation, Bioclinica's Trident IRT system triggered the initial drug shipment to the site for the first patient visit, which occurred at the site. When patients were recruited and randomized through Trident, their first site visit was scheduled (Figure 1).

- 1 During the first visit, the patient and/or caregiver received instructions for their prescription, including how and when to take each dose (AM and PM doses).
- 2 The site then completed the subject contact form and faxed it to the depot. The site also entered the visit information into Trident.
- 3 The Visit Confirmation, which included the dose information, was sent to the depot.
- 4 The pharmacist at the depot would then fill the order and ship it to the patient.
- 5 All subsequent visits were conducted by phone, and completion of data entry by the site in Trident would trigger the same dispensing process at the depot.

### Maintaining Shipping Efficiency

The kits were sent overnight within the 3-day window between the visit and drug requirement. This window was pre-planned to allow for drug delivery. If the patient was not home at the delivery attempt, another delivery was scheduled; the package was not left at the residence. The depot tracked each package very closely, particularly so appropriate plans could be made if there were anticipated or actual weather delays.

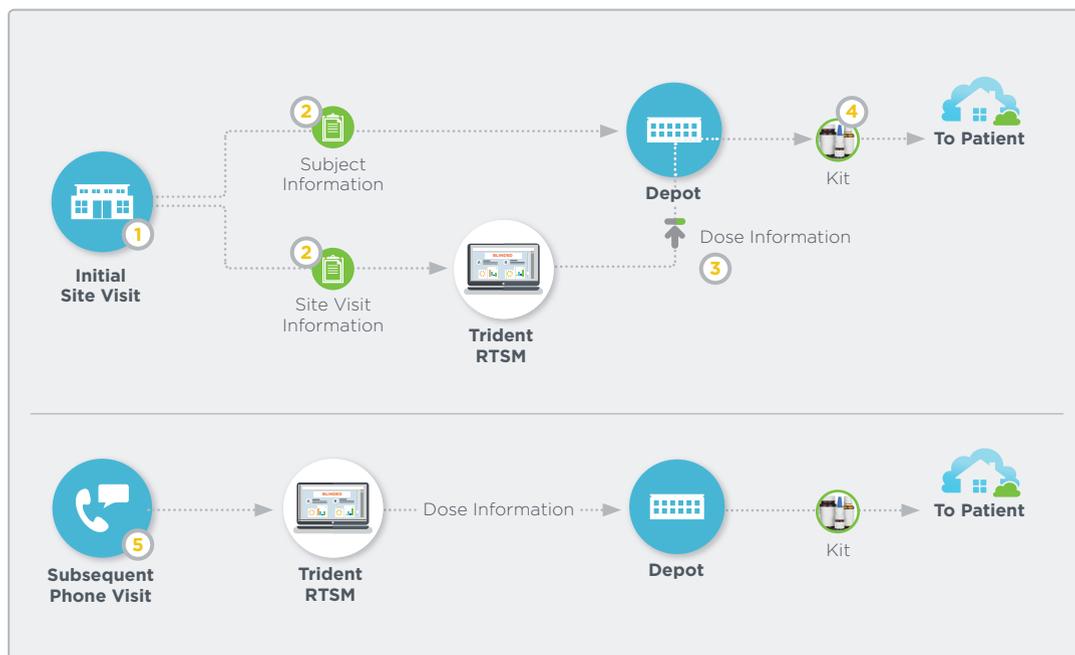


Figure 1. Process of shipping study drugs directly from the depot to the patients' after the initial site visit



## Contingencies for Incorrect Dosing Information

Mistakes can be made. During this trial, there were instances when a site entered the incorrect dosing information in Trident but recognized it before the drug was dispensed. In these cases, the site called the Bioclinica help line, who contacted the depot to stop the shipment (*Figure 2*). At the same time, the site was instructed to enter the correct information in Trident. Once the updated information was received by the depot, the correct dose was shipped to the patient's home.

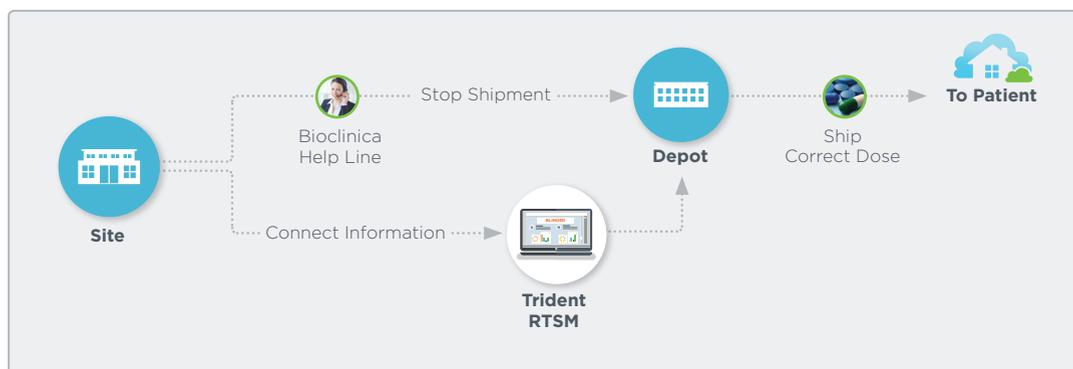


Figure 2. Contingency plan for incorrect dose information in Trident

## Outcomes

The use of direct-to-patient shipping was successfully implemented, and the drug was approved by the Food and Drug Administration after trial completion. An open-label, long-term safety trial of the same drug is now ongoing.

## Lessons Learned

Although direct-to-patient shipping can be extremely useful for reaching specific patient populations, there are certain challenges that need to be considered. This process is better suited to smaller studies with a relatively small study population. Larger Phase III trials create their own logistical difficulties. As in the present study, the process might not be possible in some countries and should be evaluated on a country-by-country basis. This also applies to the availability and selection of an appropriate depot with a pharmacist and previous experience with shipping to patients' homes. Even in the present study, the depot required inventory management by the study team; the depot would package lots in very small quantities (e.g., 20 wallets at a time). Although the depot knew its own inventory, it was not aware of the number of pending visits. Therefore, the team had to notify the depot when supplies were becoming low, so they could package more. This highlights the importance of participation by the entire study team and very clear upfront communication for a successful implementation.

## Summary

Depot-to-patient dispensing is a novel approach to the distribution of study drug that can respond to the subject's clinical needs regardless of whether the visit is conducted at the clinic or via telephone. However, successful implementation requires commitment from all parties, strong partnerships, clear communication and the flexibility and agility to respond to non-routine events.

