



## DIRECT-TO-PATIENT TOOLKIT FOR CLINICAL TRIALS

**Understanding the process, how and when to use it,  
and practical implementation strategies.**

**In This Five-Part Kit, You Will Receive:**

- Definitions for DTP Services
- An Infographic Explaining Why Studies Use DTP
- A Decision Map Outlining When DTP Should be Used
- Workflow Guides for Implementing the Process
- A Recent Case Study Illustrating Real World Application



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# WHAT IS DIRECT-TO-PATIENT



Shipping Clinical Supplies From Depot or Packaging Facility Directly to Patients Home



Shipping From Clinical Site Directly to Patients Home



Home Health Care Provider Takes Clinical Supplies to Patients Home



# WHY USE DIRECT-TO-PATIENT

## STUDY CRITERIA

- Orphan/Rare Indications
- Compassionate Use
- Phase IV Studies
- Drug Resupply
- Open Label Extension

## LOGISTICS

- Controlled Temperature
- Chain of Custody
- Maintain Good Distribution Practices to Patient Home

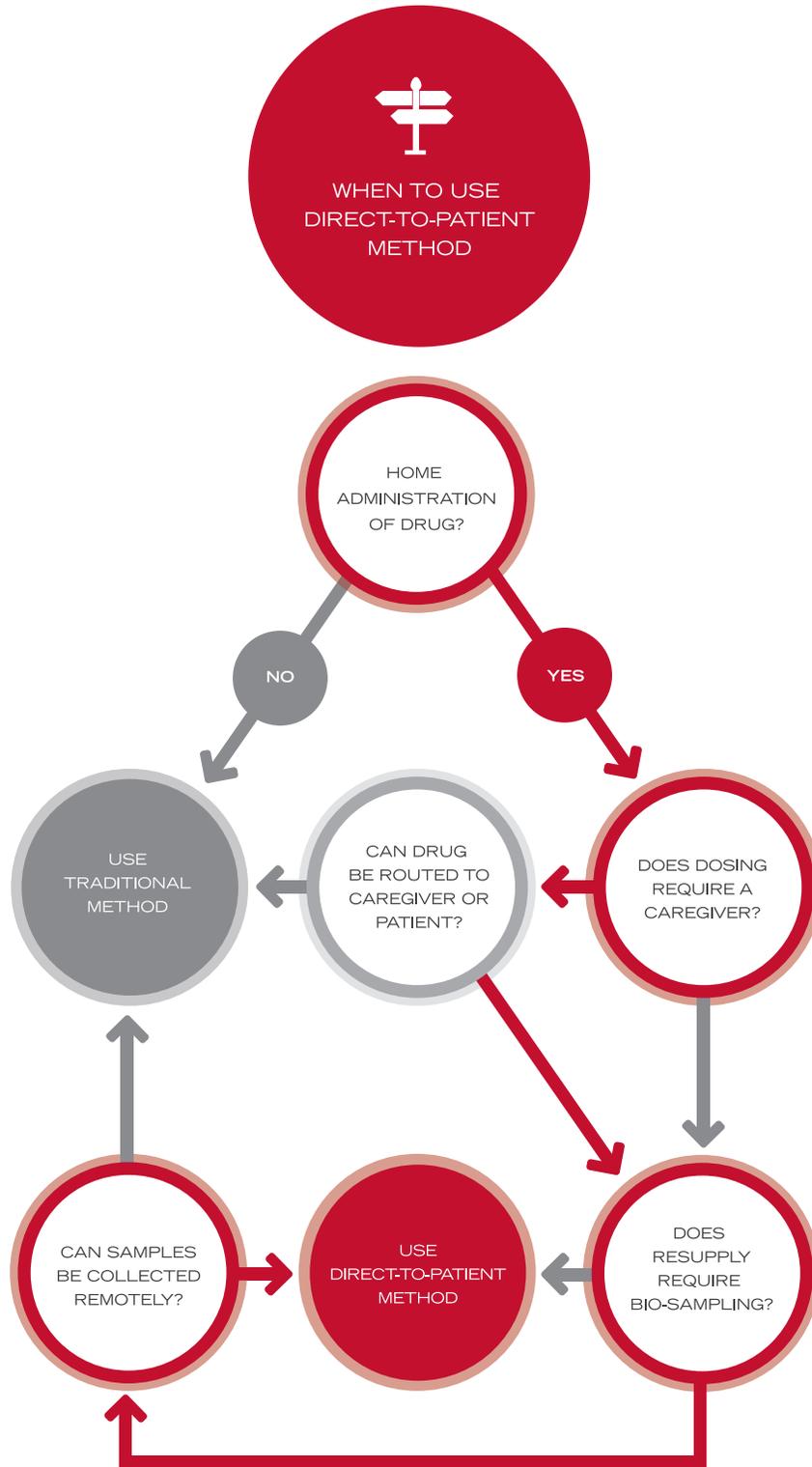
## PATIENT FOCUS

- Time Constraints
- Transport of Drug
- Patient Travel
- Homebound Patients
- Pediatric Patients
- Dispersed Patient Population



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# DIRECT-TO-PATIENT WORKFLOW GUIDELINES

When implementing a direct-to-patient shipping strategy, proper planning and coordination is extremely crucial to the study's overall success. CSM has successfully planned and executed multiple direct-to-patient clinical trials and this experience has shaped the supply chain strategy provided here and guidelines for application.

## Study Design and Set-Up

- Outline the Direct-to-Patient Process with Detailed Work Instructions at Every Step
- Determine Patient/Subject Enrollment Requirements and Notifications
- Select Logistics Partners
  - *Integrated or Premium Couriers and Transport Tools Required*
- Determine Needs of Specific Partners
  - *CTRP, Visiting Nurses, Local Pharmacies*
- Plan Distribution Model of Clinical Trial Material (CTM) to Patient
- Describe Steps For Subject Discontinuation
- Ensure GCP Compliance in the Study Design
- Receive Buy-In From All Parties
  - *PI, IRB, Sites, Sponsor, Patients*

## Patient Coordination

- Study Coordinator Provides Packager with Delivery Information
  - *Subjects Name, Address, Phone Number, and Times Available for Shipment Receipt*
- Identify Caregiver (If Needed)
  - *Remote Person From Clinical Site, Family Member, Home Health Care*
- Create a Personalized Logistics Plan Per Patient
  - *Examine Where the Patient Lives and What Couriers and/or Flights Would Work Best*
- Develop Patient Communication Chain



## Packaging Design

- Determine Drug Handling Requirements
- Prepare Individual Packages Per Patient
  - *Utilize an On-Demand Method, if Needed*

## Distribution of Clinical Supplies

- Ensure Proper Temperature is Upheld During Transit
  - *Utilize Qualified Cold Chain Shippers*
- Develop a Distribution Schedule
  - *Depending on Dosing Requirements, Drug Efficacy and Patient Availability*
- Ensure Active Monitoring of Packages
  - *Track Package Location, Temperature, When it Was Opened and for How Long*
- Plan Delivery Schedule
  - *Enough Time Built in for Actual Transit as Well as Potential Transportation Problems*

## Home Monitoring

- Train Patient and Caregivers
  - *Understand Proper Way to Accept and Return Shipment and Supplies*

### Patient Compliance

- *Ensure Patients or Caregivers Understand How to Take the Medication*
- *Study Pharmacist Contact the Patient and Provide Support on How to Dose the Medication*
- Drug Accountability
  - *If the Shipped Package is Unopened, the Clinical Packager Contacts the Clinical Study Site*

## Study Medication Return

- Returning Shippers and Medication
  - *Patients Receive Detailed Instructions on Returns Process*
- Temperature Monitoring Devices
  - *Additional Instructions are Needed For Returning Monitors*



## CASE STUDY : DIRECT-TO-PATIENT

Faced with an incredibly complicated study, CSM® took the time to create a solution that was not only effective, but almost revolutionary. The company's innovative approach to this challenging situation has confirmed its standing in the industry.

### CHALLENGES

At least five distinct challenges presented with this study, and CSM approached each one in such a way that novel solutions were found, creating successful outcomes.

- 1 The study involved an orphan indication with only two clinical sites participating in the United States. Although the sites were 1500 miles from each other, patients were dispersed around the country.
- 2 Patients participating in the study needed to be dosed three times per day for 14 consecutive days. Strict compliance with the dosing schedule was very important.
- 3 The drug product needed to be reconstituted no more than 48 hours before dosing; it would lose its efficacy after 48 hours. This restriction disallowed patients from picking up a 14-day supply from the clinical site and taking it home.
- 4 The medication is temperature controlled and must be kept at 2- to 8-degrees C.
- 5 The 36 patients are all minors, so they could not be housed at one of the two clinical sites for two weeks, away from their families.

The drug had to be delivered direct to patients, with enough time built into the delivery schedule for actual transit as well as potential transportation problems. The 14-day trial included weekends, meaning weekend delivery schedules had to be considered. The drug also had to be kept at the proper temperature during delivery.

*"This was one of the most complex issues we've ever been faced with," says Bob Albanese, Vice President of Operations. "It may even be one of the most complex studies ever for this industry."*

But CSM's whole mission is about facing complex issues head-on and finding ways to succeed where others cannot. The company's reputation is built on its ability to work in an agile mindset, embracing high variability. One of the many products offered by CSM is the On-Demand platform, where drugs are packaged and shipped only upon request.

*"We don't simply do things the way they've always been done," Albanese adds. "We take the unique thought process that created our platform and apply it to a variety of things. In this case, that platform allowed us to think creatively and find answers that otherwise may have eluded us."*



## CSM'S SOLUTION

The CSM team designed a patient kit that was reconstituted daily and shipped overnight, even on weekends. Included in the kit was a state-of-the-art temperature monitoring device that updates via cell phone service and GPS to a web-based reporting tool. Using the device allowed CSM to track the location of the package and its temperature as well as when it was opened and for how long.

Some of the main points of CSM's success include:

- New batches were made every day, utilizing CSM's On-Demand process.
- Instead of using freight integrators (whose shipping schedules don't adhere to the trial's regulations) CSM utilized commercial flights and courier services for direct-to-patient delivery.
- CSM used Credo shippers to keep the contents refrigerated correctly and a SenseAware tracking system that kept CSM apprised in real-time of the status of the package.
- A personalized logistics plan was created for each patient that examined where he or she lived and what couriers and flights would work for him/her. Kits were sent directly seven days a week.
- CSM is a TSA-certified cargo screening facility; everything is inspected before leaving the dock in Fargo and special stickers are applied so TSA knows no further inspection is necessary.
- The geo tracker used by CSM lets the package "talk" to the team. It sends an alert if it is out of temperature range or if it sits too long without being transported. It also records that it "saw" light and for how long every time the package is opened.
- If the box was not opened three times per day to get the medication, someone at CSM contacted the clinical study site.

Additionally, returns and reconciliation were able to be done right away rather than months later, the standard for most clinical trials. Because a courier delivered the next day's dosage directly the patient's home, he/she was able to pick up the return package at the same time. This verifies that the medication was taken correctly, within acceptable parameters—reconciling within 15 to 16 days of patient enrollment.

## HOW COULD CSM HELP YOU IMPLEMENT DIRECT-TO-PATIENT?

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