CSM®
A CLINIGEN COMPANY

Finding an appropriate logistics solution for the most complicated of trials

CASE STUDY:
DIRECT-TO-PATIENT SERVICES

One trial sponsor, faced with an incredibly complicated trial, asked CSM to help it develop an effective solution. Working closely with the trial sponsor, CSM created and executed a Direct-to-Patient (DtP) shipping program that enabled the trial sponsor to initiate and conduct the trial successfully.

CHALLENGES

The trial presented five fundamental challenges that, until CSM became involved, had prevented the sponsor from conducting the trial:

1. The trial involved an orphan indication with only two clinical sites in the entire United States. The patients, who were widely spread out across the country, were all minors, and so couldn't be housed for two weeks at the clinical sites.

2. Patients who participated in the trial needed to dose three times a day for 14 consecutive days. Strict compliance with the dosing schedule was extremely important.

3. The drug product needed to be reconstituted no more than 48 hours before dosing to retain its efficacy. This restriction precluded patients from picking up a 14-day supply from the site and dosing at home.

4. The drug product was temperature-controlled and needed to be kept at 2-8°C.

5. The drug product needed to be delivered directly to the patients.
    a. The delivery schedule needed to factor in for transit times, including an allowance for any transportation problems that could arise.
    b. The 14-day trial included weekends, necessitating a seven-day delivery schedule.

CSM'S SOLUTION

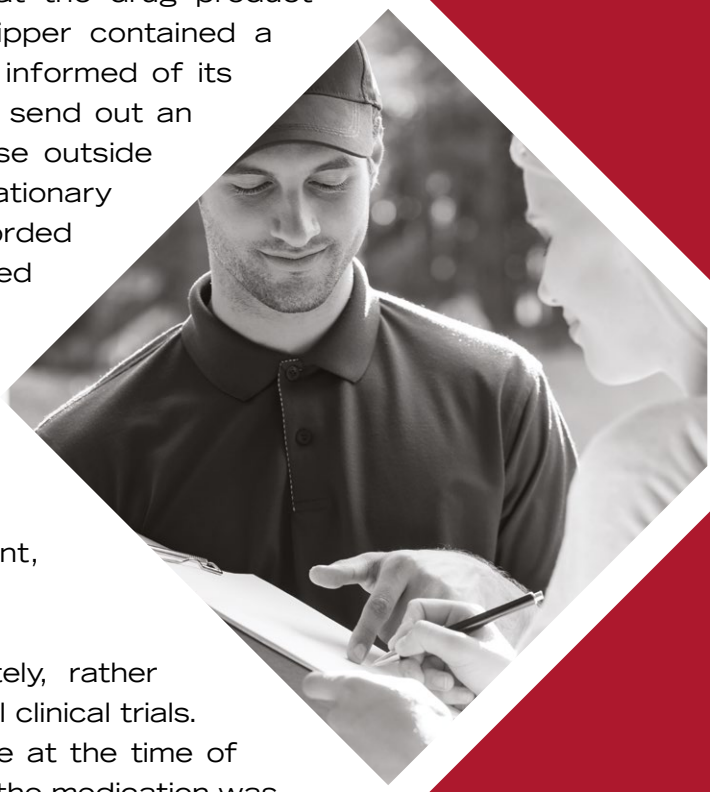
To overcome these challenges, CSM worked with the sponsor to develop a fully customized distribution plan, in which CSM:

- Prepared new batches of the drug product for daily shipment using CSM's proprietary On-Demand process.

- Combined commercial flights with courier services for Direct-to-Patient delivery, seven days a week, instead of using a standard freight integrator with a shipping schedule that would not comply with the trial requirements.

- Used its status as a TSA-certified cargo screening facility to ensure that each shipment was fully inspected before leaving CSM, so further inspections that might have delayed the shipment could be avoided.

Used customized Credo® shippers to ensure that the drug product remained correctly refrigerated. Each Credo shipper contained a SenseAware® geotracking device that kept CSM informed of its real-time status of the shipper. The device would send out an alert if the temperature of the shipper fell or rose outside the acceptable range, or if the shipper remained stationary too long without being transported. It also recorded whether the contents of the shipper were exposed to light and, if so, for how long.



Created a personalized logistics plan for each patient. Each plan factored in the address of the individual patient and which couriers or flights could be used to ship the drug product to that patient. CSM sent kits directly to each patient, seven days a week.

Implemented returns and reconciliation immediately, rather than months after the fact, as is standard in typical clinical trials. Because the courier picked up the return package at the time of the daily delivery, the trial sponsor could verify that the medication was taken correctly within 15 to 16 days of the patient's enrollment.

CSM applies its innovative and agile global capabilities and expertise to deliver direct-to-patient services.

- With over a decade of experience in managing direct-to-patient studies, CSM has worked with many trial sponsors, couriers, and clinical sites, and has developed a strong expertise in managing DtP trials.
- As a licensed research pharmacy with on-staff pharmacists, CSM understands the needs of clinical trial sponsors and their patients, and has the expertise to coordinate DtP trials and ensure their success.
- As a DtP expert, CSM is able to support you throughout the entire process, reducing the number of patient drop-outs and the overall cost of a study.

NOTE FOR EUROPEAN COUNTRIES

DtP shipments of IMPs are not widely accepted in Europe, but CSM has years of experience with DtP in the US and has developed systems and processes that can be used in Europe, should the competent authority approve it for your study. We can provide guidance on logistics and regulatory filings and support you in negotiations and meetings about DtP with the national competent authority.

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